January 30, 2023

Senator Melony Griffith, Chair
Senator Katherine Klausmeier, Vice-Chair
Senate, Finance Committee
Maryland General Assembly
3 East, Miller Senate Office Building
Annapolis, Maryland 21401
Via – Electronic Submission

RE: SB0064 (Favorable with Amendments)

Dear Chair Griffith, Vice-Chair Klausmeier, and Members of the Finance Committee:

My name is Dr. Seema Kazmi, and I am pharmacist, licensed in the State of Maryland, who has served the pharmaceutical needs of Marylanders for over 11 years. I submit this written testimony in my personal capacity.

Pharmacists have been recognized as amongst the most accessible healthcare providers, especially in rural and underserved communities, and are a key resource to ending HIV and reducing health disparities. This bill, SB0064, would allow pharmacists to prescribe PEP (post-exposure prophylaxis) for HIV. Several states in our nation, allow pharmacists to prescribe both PEP and PrEP (pre-exposure prophylaxis) for HIV, these states include: Virginia, Utah, Oregon, Nevada, Maine, Illinois, California, Idaho, and Colorado. Additional states have legislation pending.

With scientific advancements over the past 40 years, HIV treatment and preventative therapies have made a HIV diagnosis no longer the death sentence it once was. Yes, allowing pharmacists to prescribe both PEP and PrEP will increase the utilization of antiretroviral medications. However, medications for the treatment of HIV cost more, as well as treating complications and disease progression. Nevertheless, disallowing pharmacists from providing this valuable service, prescribing both PrEP and PEP, would be a setback in ending HIV.

Other states that have implemented this, have worked collaboratively with stakeholders to address concerns with follow-up and coordination of care. Pharmacists are a key partner and resource. Please find attached for the Committee's consideration different states' protocols and regulations that allow pharmacists to prescribe both PEP and PrEP for HIV.

For my patients.

Sincerely,
Seema Z. Kazmi
Seema Z. Kazmi, PharmD
Pharmacist

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COMMENTARY

Community pharmacy delivered PrEP to STOP HIV transmission: An opportunity NOT to miss!

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ABSTRACT

In the United States, 1.1 million persons are living with human immunodeficiency virus (HIV), and approximately 37,800 new infections occur annually. Ending the HIV epidemic requires reducing HIV transmissions by 90% within the next 10 years and requires expanded HIV testing, antivirals for persons infected with HIV, and scale-up of pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) to prevent new infections. Community pharmacies are widely accessible and employ highly trained health care professionals on-site who can initiate PrEP and PEP. Recommendations are offered to implement a community pharmacy PrEP program. Pharmacy, government, and HIV prevention leaders must be prepared to support and promote transformative changes, including (1) modification or expansion of existing state-specific scope of practice to initiate PrEP and PEP, (2) encouraging pharmacist education about PrEP and PEP, (3) identification and screening of candidates for PrEP eligibility, (4) incorporating pharmacy laboratory ordering and monitoring logistics, (5) adjusting workflow and ensuring confidential spaces for sensitive discussions, and (6) addressing reimbursement to maintain pharmacist-delivered PrEP and PEP programs. HIV disproportionately affects minority communities and younger individuals who may not be engaged in the health care system. Community pharmacies are accessible and can help increase PrEP use. Expansion of community pharmacy PrEP programs are needed to help end the HIV epidemic. Implementation of PrEP requires adaptation of the pharmacy profession to support incorporation of PrEP in a community pharmacy. Endorsement and support of community pharmacists are needed to implement PrEP to increase HIV prevention efforts and expand pharmacists' scope of practice.

In the United States, there are 1.1 million persons living with human immunodeficiency virus (HIV) and approximately 37,800 new annual infections.[1] In 2019, the White House announced Ending the HIV Epidemic, which will work to reduce HIV transmissions by 75% and 90% within 5 and 10 years, respectively.[2] Offering early HIV testing, antiretroviral treatment for persons infected with HIV, pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) for persons who tested negative and are at a high risk for HIV are the key drivers of success in the national plan to end the HIV epidemic.[2] Pharmacies are widely distributed in communities, have earned community trust, and have highly trained health care professionals available to increase PrEP and PEP uptake in persons who may be at the highest risk of acquiring HIV.

PrEP is safe, effective, and strongly recommended.[3-5] A single tablet of fixed dose tenofovir disoproxil fumarate/emtricitabine (F/TDF) was approved by the Food and Drug Administration (FDA) as PrEP for HIV prevention in 2012.[6] Evidence of F/TDF PrEP safety and efficacy was first published in 2010 and endorsed by the Centers for Disease Control and Prevention (CDC) the following year.[7,8] Alternative drug regimens and dosing strategies have emerged for select populations, including a coformulation of emtricitabine with tenofovir alafenamide (F/TAF), which was approved for PrEP by the FDA in late 2019 on the basis of a single trial involving men who have sex with men and transgender women.[9,10] Emtricitabine plus tenofovir alafenamide was not approved for persons at risk from receptive vaginal sex, including women and transgender men.[9] Both F/TDF and F/TAF have low

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Key Points

Background:

- Decreasing human immunodeficiency virus (HIV) transmission is a national goal.
- Despite efficacy and safety of pre-exposure prophylaxis (PrEP), use is low in those most at risk of acquiring HIV, including Blacks or African Americans, Latinos, and younger persons.
- Because of their accessibility, community pharmacies and pharmacists have the potential to increase PrEP and postexposure prophylaxis (PEP), especially in persons not engaged in the health care system.
- Two community pharmacy programs have demonstrated feasibility of pharmacist-initiated PrEP, and California's new law, SB159, will soon allow community pharmacists to initiate PrEP and PEP.

Findings:

- There is a need for pharmacists to receive additional training on HIV prevention to provide effective PrEP and PEP delivery.
- To implement an effective community pharmacy PrEP and PEP program, leaders should be prepared to increase pharmacists' PrEP and PEP education and incorporate ordering and monitoring of laboratory tests, workspace, and workflow changes as appropriate to their site.

rates of clinical adverse events when used as PrEP.[10,11] The newer formulation, F/TAF, appears to have less bone and kidney effects, although the clinical significance of these differences is unknown.[10] In addition, F/TAF has some metabolic changes in weight gain and increased low-density lipoprotein; the long-term safety of F/TAF needs further study.[12,13] A start-up syndrome involving mild nausea, abdominal cramping, or headache can occur with either F/TDF or F/TAF and is usually self-limited.[3,10] Both the World Health Organization and the CDC support the use of TDF monotherapy, which has been studied and shown to be effective in heterosexual men and women and persons who inject drugs.[4,5] For men who have sex with men, an alternative dosing strategy using F/TDF PrEP is known to be effective when 2 tablets are taken before sex, and 1 tablet is taken daily for 2 days after sex, so called "on-demand" or "2-1-1" dosing.[14] This 2-1-1 dosing strategy is endorsed by the World Health Organization and the International Antiviral Society—USA for men who have sex with men; the drug manufacturer has not submitted this evidence for FDA review in the United States.[15,16]

It is estimated that less than 10% of people who would benefit from PrEP are receiving the medication.[17] Uptake of PrEP in San Francisco, CA, and New York reached a tipping point in late 2013 after results of the nearly complete protection observed among adherent PrEP users was publicized on social media.[18,19] Use of PrEP continues to occur primarily in well-resourced cities (i.e., San Francisco), where HIV incidence is declining.[20] By contrast, HIV transmission rates are increasing in other areas, such as the rural south, where PrEP uptake is the lowest.[21,22] Barriers to PrEP uptake include lack of awareness by communities and providers, preauthorization requirements that are driven by high prices, and low access to health care services because of shortages of general prescribers and sexual health services.[23] High drug prices that prompt preauthorization requirements are a barrier to access. The wholesale acquisition cost of brand F/TDF and F/TAF is $1842.28 per person per month in the United States.[24] Generic F/TDF is expected to enter the U.S. market in September 2020, and prices may fall toward the generic F/TDF pricing available in global markets at a median $6.50 per person per month.[25,26]

Dissemination of innovations, including PrEP, require flexibility, reinvention, and local leadership.[27] With more than 60,000 community pharmacies in the United States, community pharmacies are ideal locations to reduce barriers to PrEP uptake.[28] Expanding PrEP into community pharmacies is important for HIV prevention. HIV disproportionately affects vulnerable communities, including Latinx/Latinos/Hispanics, Blacks or African Americans, and younger persons, who might not be engaged in regular medical care and show less PrEP uptake.[29,30] Community pharmacies are accessible, provide convenient and longer store hours, are staffed by pharmacists who know the medications, maintain established relationships within the community, and can offer immediate PrEP, other medications, and additional on-site patient care services (e.g., adherence counseling, vaccinations, oral contraceptives, cholesterol, and other point-of-care testing).[31,32] The convenient hours and open-door availability of community pharmacies have been shown to increase the likelihood of HIV testing in priority areas with HIV disparities, which is a key requirement for safe PrEP uptake.[33]

Objective

The objective of this commentary is to encourage key stakeholders to advocate for implementing community pharmacy–initiated PrEP and provide recommendations for implementing PrEP in a community pharmacy.

Summary

California's newest landmark legislation, SB159, mandates a state protocol for pharmacists to initiate (prescribe) and furnish PrEP and PEP.[34] This law was broadly supported and is intended to increase HIV prevention efforts in California. For ease of discussion, we refer to community pharmacy PrEP to mean a "community pharmacy PrEP program" and recommend such programs should offer both PrEP and PEP. Persons who present for PrEP may actually need PEP, and clinicians should provide PEP when indicated. Importantly, PEP must be started as soon as possible, but no later than 72 hours after the potential exposure, supporting the need for community models with immediate access to the medications.[35] Except for minor differences in medications and testing, community pharmacy PrEP implementation is similar when offering PrEP or PEP. Medication options for PEP are several and not discussed in this commentary. Pharmacists interested in providing PrEP or PEP should seek additional training to provide expert care. Implementation of PrEP and PEP in community pharmacies requires adaptation and a commitment to

Table 1
Recommendations for implementing a community PrEP program

Suggested areas	Recommended tasks
Develop a collaborative practice agreement or state protocol	- Provide pharmacists prescriptive authority to initiate and dispense PrEP and PEP prescriptions, order required laboratory tests (STI testing, serum creatinine, hepatitis B serology, hepatitis C) - Provide pharmacist autonomy
Set up laboratory logistics on-site or for send out laboratory tests	- Order CLIA-waived rapid tests - Providing pharmacy space for collecting laboratory specimens - Training staff on specimen collection and handling on-site ("one stop PrEP") or off-site - Consider on-site phlebotomist - Refer patient to outside laboratory - Access to laboratory test results
Obtain medical and sexual health history and assessment	- Develop intake questionnaire to collect medical history, sexual and drug use (if applicable), medication history, indications and potential contraindications for PrEP and PEP - Provide harm reduction counseling - Provider referrals (if appropriate) for active STI, HBV, HCV, opiate treatment or other medical condition that is suspected (i.e., high blood pressure, etc.)
Adapt pharmacy workflow and space	- Establish confidential spaces for sensitive history taking, testing, and discussion of test results - Consider installing modular ready counseling rooms for privacy - Assign specific pharmacy staff to PrEP to accommodate walk-in requests
Establish methods of communication	- Determine how important and confidential information will be shared among team members, patients, and referring providers or health departments - Set up online portals, secure e-mails, text messages, apps, and shared EMRs, which can save time
Provide and monitor pharmacist education and on-hands training, including training of any auxiliary staff	- Set up pharmacist specific training program, and as appropriate, auxiliary staff training - Pharmacists should demonstrate competency on HIV infection and the use and delivery of safe and effective PrEP and PEP per national guidelines, counseling on sexual health and comprehensive prevention strategies, especially for diverse populations who are at risk of HIV acquisition, performing laboratory tests and its proper laboratory interpretation, PrEP benefits navigation (aka coordination of benefits), including the use of manufacturer assistance programs or other free programs to reduce cost barriers for PrEP. - Set realistic time goals for patient visits, medical charting, and implementation of new work processes. - Provide feedback and ongoing training and monitoring
Identify reimbursement strategies	- Determine state reimbursement laws; modify existing laws if necessary - Consider grant funding, 340B contracts, direct negotiation with insurance contracts - Continue advocacy at the national level for recognition of provider status

Abbreviations used: CLIA, Clinical Laboratory Improvement Amendments; EMR, electronic medical record; HBV, hepatitis B virus; HCV, hepatitis C virus; PrEP, pre-exposure prophylaxis; PEP, postexposure prophylaxis; STI, sexually transmitted infection.

change. Whereas industry changes can be challenging, emerging business and health care trends require community pharmacies to adapt and develop effective new models of pharmacy care delivery. Community pharmacy leaders, administrators, and pharmacists should be prepared to acknowledge and accept that PrEP implementation in their community pharmacy might bring unique challenges that can be addressed. Table 1 summarizes recommendations, and Table 2 lists several resources for implementing PrEP.

Lessons learned from existing community pharmacy models of PrEP initiation

Under collaborative practice, pharmacists in clinical settings (e.g., ambulatory care or hospital) initiate, modify, and discontinue a number of medications, including PrEP. Several models describe pharmacists' collaboration with clinics to initiate PrEP.[36-39] Recently, 2 published models in Seattle, WA, and San Francisco (SF), CA, have demonstrated that pharmacists' initiation of PrEP in the community pharmacy setting can be successful.[40,41] The Seattle, WA, site uses a collaborative drug therapy agreement and has received financial reimbursement for initiating PrEP in more than 700 patients. The SF model operates under a collaborative practice agreement with the SF Department of Public Health to provide PrEP and PEP and was instrumental in the passage of SB159. In both of these models, the community pharmacists have the prescriptive authority to order the initial and ongoing PrEP prescriptions, obtain initial HIV and other sexually transmitted infection (STI) screening tests, have access to these laboratory test results, dispense the PrEP immediately, perform adherence counseling, and conduct follow-up monitoring. The autonomy of these pharmacists in these aforementioned models may have removed previous logistic barriers. Community pharmacists have a proven track record in the safe and effective provision of preventive care, including vaccines and contraception, therefore extending their autonomy to include PrEP is warranted.[42,43]

Securing access to laboratory test results in the community pharmacy setting is an important milestone, especially because most community pharmacies do not have access to the electronic medical record.[44] Community pharmacists can provide rapid CLIA (Clinical Laboratory Improvement Amendments)-waived tests (e.g., HIV, hepatitis C, serum creatinine, syphilis).[45] An excellent example of HIV testing in pharmacies is described by Collins et al.[33] Although the SF program has a phlebotomist, who also serves as a pharmacy technician, other pharmacies could refer out laboratory testing to reference laboratories, which is how PrEP is offered in many medical settings today. Having specimen collection on-site allows for "one stop" PrEP, which is convenient, although it requires a private room, specimen collection equipment, and a chair. Modular ready-to-install counseling rooms can be a solution for pharmacies looking to easily install a small private room.[46] Such rooms are also useful for providing confidentiality while discussing sensitive sexual history taking and drug use. National trends in

Table 2
Selected community pharmacy PrEP resources

Resource	Contact information
Community pharmacy PrEP-CPhA informational CE video (conversation with R.M.G. and M.I.L.)	https://cpha.com/ce-events/on-demand-courses/community-pharmacists-provide-prep/ (CE version) https://m.youtube.com/watch?feature=youtu.be&v=s7XcO2oD1vY (non CE, free version)
CDC Guidelines for PrEP and PEP	https://www.cdc.gov/hiv/guidelines/preventing.html PrEP for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. Updated guidelines for antiretroviral PEP after sexual, injection drug use, or other nonoccupational exposure to HIV-United States, 2016
WHO PrEP implementation toolkit	https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/
Constructing collaborative practice agreements	https://cpha.com/ce-events/on-demand-courses/cpa/ https://www.aphafoundation.org/collaborative-practice-agreements/
AIDS education and training resources	https://aidsetc.org/topics
New York state department of health AIDS Institute PrEP guidelines	https://www.hivguidelines.org/prep-for-prevention/
University of Washington training modules	National HIV Curriculum by the University of Washington, including PrEP and PEP https://www.hiv.uw.edu/ National STD Curriculum by the University of Washington https://www.std.uw.edu/ National Hepatitis training module https://www.hepatitisc.uw.edu/
Clinical consultation on PrEP and PEP	Clinician Consultation Service (https://nccc.ucsf.edu/) provide links to PrEP and PEP resources. Direct clinical consultation on PrEP and PEP, provided free by clinicians, is available by calling the PrEP line at 1-888-448-4911 (Monday–Friday, 9 AM–8 AM ET) and PEPLINE at 1-855- 448-7737 (daily 11 AM–8 PM ET)
CDC CLIA-waived testing	https://www.cdc.gov/labquality/waived-tests.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fclia%2Fwaived-tests.html
Liverpool HIV drug interactions	https://www.hiv-druginteractions.org/
CDC national PrEP locator	https://npin.cdc.gov/preplocator
PrEP locator and database	https://www.pleaseprepme.org/
PrEP resources and capacity building assistance	https://wwwn.cdc.gov/CTS Contact: get.SFcba@sfdph.org San Francisco Department of Health Capacity Building Assistance https://getsfcba.org

Abbreviations used: AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; CDC, Centers for Disease Control and Prevention; CE, continuing education; CLIA, Clinical Laboratory Improvement Amendments; CPhA, California Pharmacists Association; ET, Eastern time; PEP, postexposure prophylaxis; PrEP, pre-exposure prophylaxis; STD, sexually transmitted disease; WHO, World Health Organization.

chain pharmacies indicate expansion into the patient care footprint, including the addition of mini-clinics and laboratories, which should increase access to phlebotomy and other laboratory services in pharmacy settings.[47,48]

The community pharmacist should confirm that the patient has a negative HIV test within 7 days and before starting PrEP. The patient can bring in the results of the HIV test, or a rapid HIV finger-stick blood test can be conducted at the pharmacy. Proof of hepatitis B immunity and screening for hepatitis C, STI (e.g., gonorrhea, chlamydia, and syphilis), and serum creatinine are recommended for PrEP services, although the results of these tests are not required before initiation of PrEP.[3] Regular STI screening should be routinely completed for all persons on PrEP in accordance with CDC guidelines.[3] Patients can be taught to self-collect STI specimens for sending out or go to a nearby lab site for STI tests. Procedures for patient referral for medical care or on-site treatment should be available for all patients with preliminary positive test results or diagnosed with active STI or hepatitis B or C infections.

If pharmacies elect to collect blood and STI specimens, they will need to incorporate and integrate new and existing processes for handling laboratory specimens, using medical settings as models. One recommendation for simplifying logistics for laboratory tests' couriers is to incorporate these with preexisting medication delivery services. Nationally, most independent community pharmacies provide same-day delivery, and 2 major chains recently began to provide courier delivery services for medications.[49-51]

Collecting a sexual and drug history, a medication history for potential drug interactions, and a medical history for possible renal disease before starting PrEP can be completed by an intake questionnaire that the pharmacist reviews. The pharmacist should also rule out symptoms of acute HIV. Most persons who need PrEP are relatively young and healthy with a low risk of renal dysfunction. Questions such as, "Have you ever had a condition that affected your kidneys, a history of high blood pressure, etc.?" can screen for the possibility of preexisting renal disease. Mikati et al.[52] used similar screening questions at a PrEP clinic in New York City, NY, and found that most of the patients (97%) could start PrEP immediately.[52] For persons who are later found to have baseline renal insufficiency, it is important that they are contacted within a few days of their elevated baseline serum creatinine test results. Under these circumstances, a repeat serum creatinine test is recommended (to confirm unexpected elevations) and if confirmed, the person should be referred to a medical provider.

The disruption of pharmacy workflow could be a concern. However, such logistical concerns are common with implementation of new pharmacy services, such as vaccinations, blood pressure screenings, and laboratory testing. Community pharmacies can adapt workflow changes in a similar manner. It is best to devote staff who are not working on time sensitive preparation of medications to accommodate walk-in patients requesting PrEP. For example, staff devoted to medication therapy management and refills (future fills) are used in the

PrEP program at the SF site. During implementation, it may take staff longer to finish tasks, but efficiency should improve with increased experience. Realistic time goals for patient visits and medical charting need to be established so that PrEP staff have reasonable expectations and can adjust to the new workflows.

Community pharmacies are often separated from integrated health care systems; hence they require the establishment of partnerships for referring patients to ongoing care or to create collaborative practice agreements. Both the Seattle, WA, and SF models were able to implement shared electronic medical records at their sites. In the SF model, laboratory test results are obtained from a combination of faxes and shared electronic portal with the county health department. Many community pharmacies already use telephone calls and text messaging for refill reminders. Other time saving options for sharing of information between providers and patients include the use of secure e-mail, text messages, cell phone apps, online portals, and traditional faxes.

Pharmacy staff, similar to other medical providers, need training on PrEP, as demonstrated in several surveys.[53,54] Education should include application of the CDC PrEP (and PEP) protocols and guidelines, proper interpretation of laboratory test results, evaluation of potential drug interactions, counseling, monitoring, and follow-up. Although pharmacy school curriculum already includes interpretation of laboratory test results, competency in application is necessary and can be completed by developing a pharmacists' PrEP continuing education curriculum that includes didactic and clinical training in the delivery of PrEP. Training in the delivery of CLIA-waived tests or other laboratory procedures can be included for those sites electing to have on-site testing. Training on history taking, communicating sensitive test results, and maintaining cultural sensitivity, especially in populations most at risk is warranted. Education about PrEP benefits navigation (i.e., coordination of benefits), including the use of manufacturer assistance programs to reduce cost barriers for PrEP, is necessary. Non-PrEP staff should receive training on assisting pharmacy patients who inquire about PrEP and PEP. On the basis of a study of community pharmacists, online training is preferred.[53]

Obtaining reimbursement to cover program costs can be a challenge, especially because pharmacists are not recognized as providers at the national level through the Centers for Medicare and Medicaid Services.[55] Both the SF and Seattle sites were able to secure funding, which was key in their ability to provide PrEP services.[38,39] California's SB159 mandates to reimburse pharmacists for initiating and furnishing PrEP and PEP, but will cover only a portion of the population.[32] The California bill will reimburse at 85% of the physician rate, potentially saving health care costs. In 2016, Washington state set the gold standard for pharmacists' reimbursement when it passed landmark legislation, SB5557, which requires insurance plans to reimburse and recognize pharmacists as providers.[56] Similar reimbursement legislation has also been passed in Texas and Tennessee, paving the way for pharmacies in those states to bill for clinical services and potentially offer both PrEP and PEP.[57,58] Other means of revenue could come from contracts with 340B clinics (a government-mandated drug price rebate program for safety net providers), grant funding, and direct insurance contracts with employer groups and universities. Financial reimbursement is required for pharmacists and pharmacies to devote time and resources to these critical services, including focused counseling, confidential pharmacy space, and laboratory testing. Demonstrating pharmacists' success in providing preventive care in accessible and cost-effective ways will motivate government and health care organizations to ensure funding, similar to how vaccines and other pharmacy services have demonstrated success. Patient advocacy groups were critical to the success of SB159 in California and can also promote and urge for increased access and availability to PrEP delivery services outside of traditional medical facilities.

Conclusion

Ending the HIV epidemic will require innovative models to increase early testing and treatment, in addition to offering PrEP and PEP in an accessible manner. Embedded in the community, community pharmacies have access to persons who may be at risk of acquiring HIV and not currently engaged in the health care system. Community pharmacies serve a foundational role in taking PEP and PrEP off the shelf and putting it in the hands of people who may be exposed to HIV infection. Although providing community pharmacy PrEP services offers some new challenges, community pharmacists now are afforded a tremendous patient care opportunity to apply their training and clinical expertise in order to practice at the top of their profession and stop the HIV epidemic.

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RESOURCES

Pharmacist Prescribing: HIV PrEP and PEP

DECEMBER 9, 2022

Current Landscape

Direct Prescribing Authority:

1. California (2019): can furnish PrEP and PEP if certain conditions met
2. Colorado (2021): can prescribe drugs for conditions that have a test used to guide diagnosis or clinical decision-making and is CLIA-waived
3. Idaho (2018): can prescribe drugs for conditions that have a test used to guide diagnosis or clinical decision-making and is CLIA-waived
4. Illinois (2022): can initiate, dispense, or administer drugs for HIV PrEP and PEP via standing order by a physician or a medical director of a county/local health department
5. Maine (2021): can prescribe, dispense, and administer HIV prevention drugs pursuant to statewide protocol, standing order, or CPA
6. Nevada (2021): can prescribe, dispense, and administer drugs for preventing HIV, via statewide protocol
7. New Mexico (2020): issued new statewide protocol for prescribing PEP
8. Oregon (2021): can prescribe, dispense, and administer PrEP (and PEP in accordance with Board rules)
9. Utah (2021): prescribe PrEP and PEP (via statewide protocol or standing order)
10. Virginia (2021): initiate treatment, dispense, and administer, via statewide protocol, controlled substances for prevention of HIV, including for PrEP and PEP

Delegated Prescribing Authority/Collaborative Practice Agreements:

Beyond direct statewide prescribing authority, many states have CPA authority broad enough to allow pharmacists to prescribe PrEP and PEP for HIV prevention:

- Illinois, Michigan, Minnesota, Montana, Nebraska, New Mexico, North Dakota, South Dakota, Tennessee, Vermont, Washington, and Wisconsin

Additional Support and Publications

- HHS Ready, Set, PrEP program
- NASTAD report on pharmacist-initiated PrEP and PEP
- Proposed pharmacist role expansion in HIV prevention
- Community Pharmacy-delivered PrEP
- Benefits of rapid therapy initiation

CE Opportunities

- Powerpak: Opportunities to support PrEP/PEP efforts
- APhA: Implementing PrEP in the pharmacy

Topics: State Policy, Scope of Practice

Senate Bill No. 159

CHAPTER 532

An act to amend Section 4052 of, and to add Sections 4052.02 and 4052.03 to, the Business and Professions Code, to add Section 1342.74 to the Health and Safety Code, to add Section 10123.1933 to the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to HIV prevention.

[Approved by Governor October 7, 2019. Filed with Secretary of State October 7, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

SB 159, Wiener. HIV: preexposure and postexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for preexposure prophylaxis or postexposure prophylaxis consistent with federal guidelines. The bill would require a pharmacist, before furnishing preexposure prophylaxis or postexposure prophylaxis, to complete a training program approved by the board. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits, including pharmacist services, which are subject to approval by the federal Centers for Medicare and Medicaid Services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

This bill would expand the Medi-Cal schedule of benefits to include preexposure prophylaxis and postexposure prophylaxis as pharmacist services, as specified.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers

by the Department of Insurance. Existing law authorizes health care service plans and health insurers that cover prescription drugs to utilize reasonable medical management practices, including prior authorization and step therapy, consistent with applicable law. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, existing law prohibits plans and insurers, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.

This bill would additionally prohibit plans and insurers from subjecting antiretroviral drugs, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except that if the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, the bill would instead require the plan or insurer to cover at least one of the therapeutically equivalent versions without prior authorization or step therapy. The bill would also prohibit plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing preexposure prophylaxis or postexposure prophylaxis, except as specified. The bill would prohibit plans and insurers from covering preexposure prophylaxis that has been furnished by a pharmacist in excess of specified amounts. Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the

enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(ii) Nicotine replacement products, as authorized by Section 4052.9.

(iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

SEC. 2. Section 4052.02 is added to the Business and Professions Code, to read:

4052.02. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity.

The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 3. Section 4052.03 is added to the Business and Professions Code, to read:

4052.03. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "postexposure prophylaxis" means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation

with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 4. Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:

1342.74. (a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for

the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

SEC. 5. Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:

10123.1933. (a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

SEC. 6. Section 14132.968 of the Welfare and Institutions Code is amended to read:

14132.968. (a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel medications, as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone hydrochloride, as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in subdivision (a) of Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering immunizations, as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement therapy, as authorized in Section 4052.9 of the Business and Professions Code.

(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years.

(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section neither restricts nor prohibits any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations

in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

SB159

California Pharmacists Initiation of PrEP and PEP in a pharmacy

In 2019, California passed SB159 legislation to allow pharmacists to initiate important HIV prevention medications to reduce HIV risk and incidence.

SB159 KEY HIGHLIGHTS

- Allows pharmacists to independently initiate and furnish PrEP for up to 60 days and PEP for 30 days.
- Mandates Medi-Cal (California Medicaid Program) to reimburse pharmacist services for PrEP and PEP.
- Prohibits Prior Authorizations on PrEP medications to facilitate medication access.

Under SB159, a pharmacist may furnish a 30-60 day supply of PrEP if all of the following requirements are met:

1. **Patient is HIV negative, documented within prior 7 days.**
   - Test can be Ab only or Ag/Ab or FDA approved rapid finger stick blood Point of Care test. If test result is not provided by the patient, pharmacist should order HIV test.
2. **Patient does not have signs/symptoms of acute HIV on a self-reported checklist.**
   - Symptoms of acute HIV include: flu-like symptoms such as fever, fatigue, myalgias, pharyngitis, cervical adenopathy, night sweats, diarrhea, and rash.
3. **Patient does not report taking any contraindicated medications.**
4. **Pharmacist provides counseling to patient regarding ongoing use of PrEP, which may include:**
   - Counseling on side effects and adherence
   - Importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, STIs, and pregnancy
   - Safety during pregnancy and breastfeeding
   - Notify patient they must be seen by a PCP for ongoing prescription and that a pharmacist can only furnish a 60-day supply of PrEP once every 2 years
5. **Services provided must be documented in the patient record in the pharmacy.**
6. **Pharmacist should not furnish more than a 60-day supply once every 2 years to a patient.***
7. **Pharmacist should notify patient's PCP, unless the patient does not have one or refuses consent. The pharmacist should then provide a list of physicians and clinics for PrEP.**
8. **The patient cannot waive the consultation.**

*Unless otherwise directed by a prescriber or under collaborative practice agreement.

Pharmacist can furnish a full 30-day course of PEP if all of the following requirements are met:

1. **Pharmacist determines the HIV exposure occurred within the past 72 hours and the patient meets clinical eligibility for PEP consistent with CDC guidelines.**
2. **Pharmacist provides HIV testing that is classified as CLIA waived or determines patient is willing to undergo HIV testing consistent with CDC guidelines.**

   If patient refuses to undergo testing but is otherwise eligible for PEP, pharmacist can still provide PEP.
3. **Pharmacist provides counseling to patient on the use of PEP consistent with CDC guidelines, which may include:**
   - Side effects, safety during pregnancy and breastfeeding, adherence, and importance of timely testing and treatment, as applicable for HIV, renal function, hepatitis B, hepatitis C, STIs, pregnancy
   - Inform the patient on the availability of PrEP for persons who have ongoing risk of HIV acquisition.
4. **Pharmacist should notify patient's PCP, unless the patient does not have one or refuses consent. The pharmacist should then provide a list of physicians and clinics for PEP.**
5. **The patient cannot waive the consultation.**

Checklist for implementing SB159

- Complete 90-minute Continuing Education requirement.
- Become familiar with CDC PrEP and PEP Guidelines.
- Consider HIV testing options for PrEP and PEP patients in the pharmacy.
- Compile referral lists for lab-based testing, ongoing PrEP providers, substance use services, and social support.

HIV testing in the pharmacy setting

- CDC recommends laboratory 4th generation Ag/Ab test or rapid, point-of-care fingerstick blood test.
- Rapid HIV tests can be conducted in a pharmacy that obtains a CLIA waiver certificate, allowing patients to access same-day PrEP starts.
- Trained staff members may perform CLIA-waivered point-of-care testing. Consider utilizing a phlebotomist under collaborative practice or referring patients to a nearby laboratory.

Where can pharmacists complete PrEP and PEP training for SB159?

- California State Board of Pharmacy: **www.bit.ly/CApharm_PrEP**
- California Society of Health System Pharmacists: www.bit.ly/cshp_training
- California Pharmacists Association: www.bit.ly/cpha_course

How can pharmacists connect patients to long term PrEP care?

- Partner with local Community Based Organizations that provide navigation services to long term PrEP care.
- Compile a referral list of local PrEP care providers and other social support services.
- PrEP provider locator can be found at **www.preplocator.org**.

POPULATION HEALTH DIVISION
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

5/2022

PrEP in a Pharmacy

Pharmacists can initiate PrEP and PEP to prevent HIV and reduce health disparities*

What are PrEP and PEP?

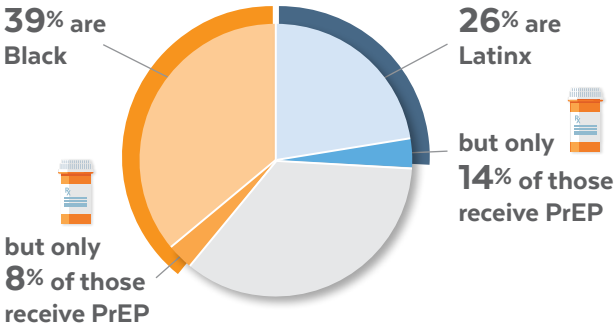
- PrEP is medication that when used correctly **can reduce the risk of HIV through sexual transmission by 99%** and can also prevent HIV transmission through injection drug use.
- PEP is a 3-drug HIV medication regimen for 28 days, that can be started within 72 hours of a possible exposure to HIV to prevent HIV infection, in persons who are not taking PrEP.
- See page 4 for recommended PrEP and PEP regimens.

PrEP can reduce the risk of HIV by 99%.

Pharmacy PrEP is an opportunity to decrease disparities in HIV prevention

- Pharmacies are accessible to people not engaged in the healthcare system.
- Pharmacists can increase PrEP and PEP awareness and uptake of these two HIV prevention tools.
  - Tip: Start discussions with patients by asking, *"Have you heard of PrEP?"; "Do you know what it does?"*
- Having the medication on hand is important for timely access to PrEP and PEP.
- Pharmacies can help enroll patients in programs to pay for PrEP and PEP and assist with cost barriers.

ACCORDING TO THE CDC, OF THOSE ELIGIBLE FOR PREP...[1]



Pharmacists can initiate and furnish PrEP and PEP

- Under California SB159, pharmacists may furnish a 30-day course of PEP and up to a 60-day supply of PrEP.
  - See the attached SB159 guide for implementation requirements.
  - Refer to primary care or other provider for ongoing PrEP care.
- Pharmacists can set up Collaborative Practice Agreements with physicians to allow for all steps of ongoing PrEP care to take place in a pharmacy.

Who may benefit from PrEP?

- Anyone who self-identifies a need for PrEP
- Men who have sex with men (MSM)
- Trans women
- People with sex partners who are living with HIV or at risk for HIV
- People who inject drugs or use stimulants during sex
- People who have had a sexually transmitted infection (STI)
- People who have condomless anal or vaginal sex

*A pharmacy PrEP program should include both PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) for HIV.

Process for pharmacist initiation of PrEP and PEP and ongoing monitoring

Take a sexual, medical, and substance use history.

Use the Five P's: Partners, Practices, Prevention of Pregnancy, Protection from STDs, and Past History of STDs.

Screen for acute HIV infection.

Recent history of fever with sore throat, rash, or headache?

YES

- Refer to testing for acute HIV (HIV Ag/Ab laboratory test and HIV-1 RNA test).
- Consider deferring PrEP until test results are back.

NO

Obtain a negative HIV test result within 7 days before starting PrEP.

- CDC recommends HIV Ag/Ab lab test **AND** HIV-1 RNA test for patients who used PrEP in the last 3 months. A rapid HIV Ag/Ab or HIV Ag/Ab lab test can be used for patients with no PrEP use in the last 3 months.
- Rapid fingerstick HIV Ag/Ab test can be done in a pharmacy with a CLIA waiver.

  Note: Pharmacists should initiate nPEP even if rapid tests results are not available.
- CDC also recommends blood draw for creatinine or rapid creatinine test.

HIV test negative

HIV test positive

Do not start PrEP; refer for HIV treatment.

Order other baseline testing:
STIs, HBV, HCV, kidney function, pregnancy test

Pharmacists providing PrEP under CA SB159 should refer patients to a provider for these tests, or pharmacists can order them under a Collaborative Practice Agreement.

Provide PrEP or PEP and counseling. Arrange for 60-90 day follow up. Repeat testing at 4-6 weeks for nPEP.

- Data suggests that offering same day PrEP starts may help with retention.
- **Provide** PEP for patients with a potential HIV exposure in the prior 72 hours.

Complete referrals to PCP, STI clinic, navigation, and other community services needed.

Partnership with Community Based Organizations for navigation services and other social needs can support adherence to PrEP.

CDC recommended oral PrEP baseline and follow up testing

Test	Initiation	Q3	Q6	Q12	Comments
Assess HIV risk and PrEP indication	✓	✓		✓	Assess HIV risk by collecting medical, sexual, drug use history, and drug-drug interactions every 3 months. Assess appropriateness of therapy at least annually.
HIV test and screen for signs of acute HIV	✓	✓			• Negative HIV test must be obtained within 7 days before initiation. • CDC recommends HIV Ag/Ab laboratory testing. Consider providing rapid fingerstick HIV Ag/Ab blood test for same day PrEP starts if no PrEP use in last 3 months. • Order HIV-1 RNA test if patient has used PrEP in last 3 months or if concern for acute HIV.
Renal function (CrCl)	✓		✓	✓[a]	If other risks for decreased renal function exist (i.e. diabetes, hypertension), conduct more frequent renal monitoring.
Lipid panel test	✓			✓[b]	Monitor weight gain.
HBV serology	✓				Obtain HBsAg or documentation of vaccine history before initiation. **Note**: Per CDC, do not withhold PrEP initiation while obtaining Hep B status.
HCV screening	✓			✓	Conduct rapid point of care HCV test or lab-based testing.
Pregnancy test	✓	✓			Conduct pregnancy test in persons of childbearing potential.
STI testing	✓	✓	✓		• Assess for signs and symptoms of STIs. Order syphilis, gonorrhea, and chlamydia tests, with frequency of 3-6 months depending on risk factors. • For MSM and trans men and women, 3-site gonorrhea and chlamydia testing should be completed, and self-collection is encouraged.
PrEP counseling	✓	✓			Include medication adherence counseling, importance of timely follow up, and sexual health counseling.
Additional prevention services	✓	✓			• Provide harm reduction for injection drug use and offer naloxone for people who use opioids. • Recommend providing vaccinations including hepatitis A and B, meningococcal, COVID-19, and HPV as indicated.

[a]Q12 months for persons < 50 years and eCrCL > 90 ml/min; Q6 months for all other persons. [b]for F/TAF

PrEP oral medications[a]

There are a variety of PrEP pill sizes and colors.

	Tenofovir disoproxil fumarate (300 mg)/ emtrictabine (200 mg) F/TDF (generic or Truvada®)	Tenofovir alafenamide (25 mg)/ emtricitabine 200 mg F/TAF (Descovy®)
Dosing[b]	1 pill orally once daily	1 pill orally once daily
Approved for	Persons weighing 35kg or greater, for any PrEP indication including sexual transmission or injection drug use	Men who have sex with men (MSM) and trans women weighing 35kg or greater, but not for receptive vaginal sex or injection drug use
Side effects	• Generally safe and well tolerated • Some people have gas, nausea or headache. These symptoms often go away within the 1st month. • Small changes in kidney function measurement and bone mineral density can occur, but are generally not deemed clinically significant	• Generally safe and well tolerated • Some people have gas, nausea or headache. These symptoms often go away within the 1st month. • Small increases in LDL cholesterol • Small increases in body weight
Safety considerations	• Not recommended for those with chronic kidney disease and eGFR <60 ml/min • Caution in those with osteoporosis	• Not recommended for those with chronic kidney disease and eGFR <30 ml/min

[a]Long-acting injectable cabotegravir can be administered every 2 months for PrEP.
[b]Under SB159, pharmacists are authorized to provide up to a 60 day supply. CDC recommends providing a 90 day supply, which pharmacists may provide through a Collaborative Practice Agreement.

PEP medications

OPTION 1

F/TDF

1 tablet PO daily*

+

Dolutegravir 50mg

1 tablet PO daily

OPTION 2

F/TDF

1 tablet PO daily*

+

Raltegravir 400mg

1 tablet 2x daily

OPTION 3

Bictegravir/F/TAF

Recommended regimens. Alternative regimens can be found in PEP CDC guidelines and by contacting the National PEP Line, nccc.ucsf.edu.

*if renal function eGFR >60 ml/min

What if my patient has a positive HIV test on PrEP?

- Discontinue PrEP immediately to avoid HIV resistance.
- Determine last time they took PrEP and assess overall adherence.
- If initial test returns positive, conduct confirmatory testing or refer for confirmatory testing.
- Patients who test positive should be linked to care with a local HIV treatment provider, ideally same day for rapid initiation of ART (antiretroviral therapy). Rapid initiation of ART is the recommended best practice.
- Compile a list of local HIV medical providers to refer patients who test positive. A directory of HIV providers based on location can be found at **www.findhivcare.hrsa.gov**.

Trainings fulfilling SB159 requirements:

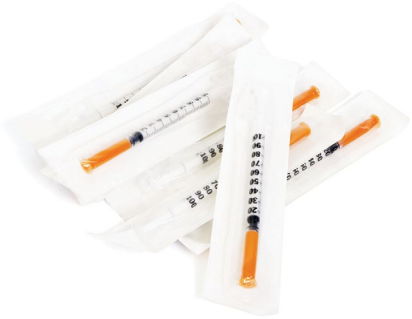
- **California State Board of Pharmacy:** www.bit.ly/CApharm_PrEP
- **California Society of Health System Pharmacists:** www.bit.ly/cshp_training
- **California Pharmacists Association:** www.bit.ly/cpha_course

Additional PrEP training resources:

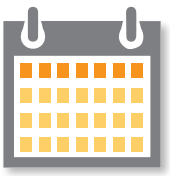
- **American Pharmacists Association:** www.bit.ly/apha_implementingPrEP
- **PRIME education:** www.bit.ly/prime_PrEP
- **PowerPak:** www.bit.ly/PowerPak_course
- **Pharmacy Today:** www.bit.ly/PharmToday_implementingPrEP

What additional prevention services can pharmacists provide?

- Provide onsite HIV testing services and education on HIV prevention.
- Supply new syringes and needles to people who inject drugs to prevent bloodborne infections including HIV and HCV, and refer to syringe service programs.
- Furnish naloxone to people who use opioids to help reduce overdose deaths.
- Offer vaccinations for COVID-19, influenza, hepatitis A and B, and other communicable diseases.



Recommendation for same day pharmacy PrEP starts:



- Patients are more likely to start PrEP and continue taking it when they can start medication the same day as the visit.
- HIV test must be confirmed negative within 7 days prior to PrEP initiation. All other labs should be ordered at initiation and obtained within 7-10 days after initiation.

Steps to offering PrEP and PEP in a pharmacy*

Areas of practice	Recommended tasks
Develop a collaborative practice agreement	• Required for long term PrEP care in a pharmacy, but not required for PrEP or PEP initiation through SB159. • Provides pharmacists prescriptive authority to initiate and dispense PrEP and PEP medications and order required laboratory tests for ongoing PrEP care.
Set up laboratory logistics	• Order CLIA-waived rapid HIV tests. • If collecting lab specimens onsite: provide pharmacy space for collecting lab specimens, consider on-site phlebotomist, and train staff on specimen collection and handling. • If referring off-site, identify outside laboratory for specimen collection. • Ensure access to laboratory results.
Obtain medical and sexual health assessment	• Finalize intake questionnaire to collect medical, sexual and drug use history, and potential contraindications for PrEP and PEP. • Provide harm reduction counseling. • Provide referrals for active medical conditions (STI, HBV, HCV, substance use treatment) as needed.
Adapt pharmacy workflow and space	• Establish confidential space for sensitive history taking, testing, and discussion of test results. • Consider installing modular ready counseling rooms for privacy. • Set realistic time goals for patient visits and charting.
Establish methods of communication	• Determine how confidential information will be stored and shared among team members, patients, referring health providers, and health departments. • Set up access to secure online portals, EMR, texts, or emails.
Provide and monitor education and training for pharmacists and auxiliary staff	• Set up pharmacist training program, and as needed, auxiliary staff training. • Training should include competence in PrEP & PEP guidance, counseling on sexual health, serving diverse populations at risk for HIV, and PrEP benefits navigation. • Provide feedback and ongoing training and monitoring.
Identify reimbursement strategies	• Stay up-to-date on state reimbursement laws. • Consider grant funding, 340b contracts, negotiations with insurance contracts.

*Adapted and updated from MI Lopez, et al. *J Am Pharm Assoc.* 2020 Jul-Aug;60(4):e18-e24.

How will patients pay for PrEP and PEP?

- Private insurance and Medi-Cal are required to cover PrEP and PEP medications, and most plans in California now pay for PrEP with $0 cost-sharing.
- Multiple generics for F/TDF are now available, and generic F/TDF for PrEP should not be subject to prior authorization by California-based insurance plans.
- Co-pay assistance can be found through manufacturers and other programs:
  - Patient Advocate Foundation if <400% of FPL: **www.copays.org**
  - PAN Foundation if <500% of FPL: **www.panfoundation.org**
- Uninsured patients can access medications through the federal Ready, Set, PrEP program (**www.getyourprep.com**) or manufacturer assistance programs (MAPs) through Gilead, Merck, and VIIV, the manufacturers of PrEP and PEP medications.
- For patients who are fully enrolled in the California PrEP Assistance Program (PrEP-AP), PrEP-AP provides coverage, or wrap around coverage, of medications on the PrEP-AP formulary and allowable PrEP-related medical services.
  - Enrolled patients can get PrEP and PEP medications through ADAP/Magellen network pharmacies.
  - For PEP, call 844-421-7050 Mon-Fri 8am-5pm, **www.bit.ly/cdph_prepAP**
  - Pharmacies can contract with the California Department of Public Health to be a PrEP-AP Temporary Coverage Enrollment Site. Pharmacies approved for the program can enroll eligible patients in PrEP-AP for temporary and limited coverage of PrEP, PEP, and certain allowable PrEP-related medical services.

Start by asking the patient: *"Do you have prescription insurance?"*

YES

Has card

- Test claim. If in-network, can fill onsite. If out-of-network, consider calling in prescription to an in-network pharmacy.
- Activate co-pay card if needed.

No card

Obtain identifiable info including SSN to run benefits check.

YES, but...

I have a confidentiality concern with using insurance I have through a parent, spouse, or registered domestic partner.

—OR—

I am 12-17 years of age.

- If a client is a minor (age 12-17) or has confidentiality concerns with using insurance, they may be eligible to enroll in PrEP-AP through a PrEP-AP Enrollment site or a PrEP-AP Temporary Coverage Enrollment Site.
- If PEP, call PrEP-AP (844-421-7050) Mon-Fri 8am-5pm for immediate enrollment.

NO

Uninsured clients may enroll in PrEP-AP Temporary Coverage regardless of income.

However, not all pharmacies that furnish PrEP/PEP are contracted to be Temporary Coverage Enrollment Sites.

Pharmacist PrEP resources

Centers for Disease Control and Prevention Capacity Building Assistance Western Region	• San Francisco Department of Health Capacity-Building Assistance: www.getsfcba.org. Contact: get.SFcba@sfdph.org • wwwn.cdc.gov/CTS
Clinical consultation on PrEP and PEP	• Clinician Consultation Service (online resources): www.nccc.ucsf.edu • Direct and free clinical consultation on PrEP and PEP is available: PrEP line at 888-448-4911 (Mon–Fri, 9 am–8 pm ET) PEP line at 855-448-7737
Centers for Disease Control and Prevention Guidelines for PrEP and PEP	• www.cdc.gov/hiv/guidelines/preventing.html • Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. • Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016
WHO PrEP toolkit	www.who.int/tools/prep-implementation-tool
Constructing collaborative practice agreements	• www.cpha.com/ce-events/on-demand-courses/cpa • www.aphafoundation.org/collaborative-practice-agreements
AIDS education and training	www.aidsetc.org/topics
AIDS Drug Assistance Program (ADAP)	www.bit.ly/adap-sites
University of Washington training modules	• National HIV Curriculum, including PrEP and PEP: www.hiv.uw.edu • National STD Curriculum: www.std.uw.edu • National Hepatitis training module: www.hepatitisc.uw.edu
CDC CLIA waived testing	www.bit.ly/waived-tests
Liverpool HIV drug interactions	www.hiv-druginteractions.org
CDC National PrEP locator	www.preplocator.org
PrEP-AP enrollment sites	www.bit.ly/prep-ap-sites
LGBTQ education	• GLAAD tips for allies: www.glaad.org/about • LGBTQ Health Education: www.bit.ly/LGBTQIA_edu
CA state and county PrEP sites *(List is not all inclusive. Contact counties for updated resources.)*	• California Department of Public Health: www.bit.ly/cdph_prep • Los Angeles County: getprepla.com/centers-of-excellence • San Diego County: www.bit.ly/SanDiego_HHSA • San Francisco County: www.askaboutprep.org
Planned Parenthood	www.plannedparenthood.org
CA PrEP advocacy sites *(Please check with your county for additional resources.)*	• AIDS Program of Los Angeles: www.prepexpress.org • Los Angeles LGBT Center: www.prephere.org • San Francisco AIDS Program: www.sfaf.org/services/prep

1. National Center for HIV, Viral Hepatitis, STD, and TB Prevention AtlasPlus surveillance data. www.cdc.gov/nchhstp/atlas. Accessed April 12, 2022.

Appendix C

Colorado State Board of Pharmacy Statewide Protocol

Pre-Exposure and Post-Exposure Prophylaxis of HIV

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the U.S. Centers for Disease Control and Prevention (CDC)[1, 3] and the United States Preventive Services Task Force (USPSTF)[2].

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Colorado

2. Be engaged in the practice of pharmacy

3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist

4. Carry adequate professional liability insurance as determined by the Board

5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.)

6. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.

B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

Pre-Exposure Prophylaxis (PrEP) Protocol

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table Ia, or other

FDA approved/CDC recommended medications or regimens can be used if they become available, according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care antigen/antibody fingerstick blood test, or by drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test with results being received within 7 days prior to the initiation of PrEP. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

   a. Sexually-Active Adults
      - HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
      - Has tested positive for bacterial STI in the past 6 months

   AND at least one of the following:
      - HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
      - Has tested positive for bacterial STI in the past 6 months
        - Gonorrhea, Chlamydia, and Syphilis for men who have sex with men (MSM) and transgender women (TGW) who have sex with men, including those who inject drugs
        - Gonorrhea and Syphilis for heterosexual women and men including persons who inject drugs

   b. Persons Who Inject Drugs (PWID)
      - Adult person
      - Without acute or established HIV infection
      - Any injection of drugs not prescribed by a clinician in past 6 months

   AND any of the following:
      - Any sharing of injection or drug preparation equipment in past 6 months
      - Risk` of sexual acquisition (see above)

   c. Any patient who requests PrEP, even if no specific risk behaviors are elicited

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:
- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest acute HIV infection not yet detectable (fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, diarrhea)
- Patients on medications contraindicated with PrEP therapy selected
- Patients with history of hypersensitivity reaction to PrEP therapy selected

TABLE 1a – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available.

Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Frequency	Duration of Therapy	Notes
FTC/TDF (F/TAF) emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <60 ml/min.
FTC/TAF (F/TAF) emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert.

CAB Cabotegravir 600mg/3mL (Apretude®) extended-release injectable suspension for intramuscular (IM) use	>35kg	Month 1: 4-week optional oral lead in of daily cabotegravir 30mg (Vocabria®) tablet Month 2: 600mg (3mL) IM gluteal injection administered by healthcare professional on last day of oral therapy or within 3 days of last oral dose Month 3 (and every 2 months thereafter): 600mg (3ml) IM gluteal Injection administered by healthcare professional	Prescription issued for 1 injection at a time following the dosing and lab schedule	See package insert for instructions regarding planned or unplanned missed injections Drug resistant HIV-1 variants have been identified with use of Apretude® (Black Box Warning)

Labs:

- PrEP cannot be started without a negative HIV Ag/Ab test at baseline.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.
- PrEP refills will not be authorized past the initial 30 day supply for oral therapy if recommended baseline testing is not done by one of the above mechanisms.
- PrEP refills will not be authorized in absence of scheduled follow up for injectable therapy

TABLE 2a – ROUTINE REQUIRED MONITORING OF INJECTABLE TREATMENT

Test	Frequency	CDC recommendations	Notes
HIV (Ag/Ab & HIV 1 RNA assay	Baseline + Prior to each injection + when stopping CAB	**Required**	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + Every 4 months (starting with 3rd injection) for MSM & TGW Every 6 months (starting with 5th injection) for heterosexually-active persons When stopping CAB (only for MSM, TGW)	Recommended	If positive – refer for care
Need to continue PrEP	Annually	Recommended if at continued risk	Discuss with patient

TABLE 2b-ROUTINE REQUIRED MONITORING OF ORAL TREATMENT

Test	Frequency	CDC Recommendations	Notes
HIV Ag/Ab	Baseline + Every 3 months	Required	If positive, refer
HIV-1 RNA assay and assess for signs/symptoms of acute HIV infection	Every 3 months + when stopping PrEP	Required	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + Every 3 months + when stopping PrEP for MSM & TGW Every 6 months for heterosexually-active persons	Recommended	If positive, refer for care

Serum creatinine	Baseline + Every 6 mo. If age ≥50 or eCrCL <90 mL/min at PrEP initiation Every 12 mo. If continuing PrEP + When stopping PrEP	Recommended	If CrCL <60 mL/min, cannot use F/TDF If CrCL <30 mL/min, cannot use F/TAF If rapid decline in kidney function, consult nephrology
Weight, Lipid panel (if taking F/TAF)	Baseline, + Every 12 months	Recommended	
Hepatitis B screening	Baseline	Recommended	If positive – refer for care
Need to continue PrEP	Annually	Recommended if at continued risk	Discuss with patient

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted infections.
- For injectable cabotegavir: the long drug "tail" of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug resistant strain of HIV during this time. To help patients safely discontinue CAB PrEP injections pharmacists should:

  • Re-educate patients about the tail and the risks during declining CAB levels

  • Asses ongoing risk/indications

  • If PrEP is indicated prescribe oral F/TDF or F/TAF beginning with 8 weeks after last injection

  • Educate about nPEP

  • Conduct HIV-1 RNA tests at each quarterly follow up visit after discontinuation ofCAB injections and discuss the importance of keeping these follow up appointments

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.

- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv

- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- If a female patient becomes pregnant while on PrEP

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. nPEP must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. nPEP should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. PEP providers in Colorado include the STD Clinic at Denver Public Health (303.602.3540) and local emergency departments (CDPHE to comment).

If the following criteria are met, antiretroviral agents in Table 3a are recommended:

- The exposure must have occurred within 72 hours

- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.

- Exposure to a source individual known to be HIV-positive. Exposure of:

- Vagina
- Rectum
- Eye
- Mouth
- Other mucous membranes
- Nonintact skin
- Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

WITH

- Blood
- Semen
- Vaginal secretions
- Rectal secretions
- Breast milk
- Any body fluid visibly contaminated with blood

- Exposure types with the highest risk of transmission of HIV are:
  - Needle sharing during injection drug use
  - Percutaneous needle stick
  - Receptive anal intercourse
- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 3a may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP

- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services MUST be contacted.

  Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at https://www.ccasa.org/gethelp/health-related-organizations/

- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-844-CO-4-KIDS.

TABLE 3a – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Dose	Duration of Therapy	Notes
PREFERRED REGIMEN				
emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) **PLUS** **raltegravir 400mg** **OR** **Dolutegravir 50mg**	≥ 13 years	Once daily #28 no refills Twice daily #56 no refills Once daily #28 no refills	28 days	Dosing adjustments with renal dysfunction if CrCL <60 ml/min. Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used.

TABLE 4a – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is. If the patience refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

- Ask the following screening question:

    o Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

    In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.

- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

Test	**Frequency**	**CDC recommendations**	**Notes**
HIV	Baseline + Post-exposure at week 4-6, and months 3 and 6	**Required**	If positive, refer.
STI screenings (syphilis, gonorrhea, chlamydia)	Baseline	Recommended	If positive – refer for care
Serum creatinine	Baseline + @4-6 weeks.	Recommended	
ALT/AST	Baseline + @4-6 weeks.	Recommended	
Hepatitis B screening	Baseline + 6 mo	Recommended	If positive – refer. If negative and clinically appropriate, vaccinate
Hepatitis C screening	Baseline + 6 mo	Recommended	If positive - refer
Pregnancy	Baseline + @4-6 weeks.	Recommended	Pregnancy is not a contraindication to NPEP

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)

- The importance of medication adherence with relation to efficacy of nPEP

- Signs/symptoms of acute HIV infection and recommended actions

- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment

- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed

- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases

- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.

- The pharmacist will also follow all documentation rules in Rule 17.

Referrals:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv

- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv

- If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv

- Signs of symptoms of acute drug toxicities or serious side effects

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

[1]CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2021 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/112360

[2]USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

[3]CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use or Other Nonoccupational Exposure to HIV – United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856

SENATE BILL 21-094

BY SENATOR(S) Ginal and Winter, Buckner, Fields, Jaquez Lewis, Kirkmeyer, Simpson, Pettersen;
also REPRESENTATIVE(S) Roberts and Ortiz, Bird, Hooton, Lontine, Michaelson Jenet, Mullica, Snyder, Young.

CONCERNING THE CONTINUATION OF THE STATE BOARD OF PHARMACY, AND, IN CONNECTION THEREWITH, IMPLEMENTING RECOMMENDATIONS CONTAINED IN THE 2020 SUNSET REPORT BY THE DEPARTMENT OF REGULATORY AGENCIES AND MAKING OTHER CHANGES REGARDING THE PRACTICE OF PROFESSIONS REGULATED BY THE BOARD.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, 12-280-104, **amend** (3) as follows:

12-280-104. State board of pharmacy - creation - subject to review - repeal of parts. (3) ~~Parts 1 to 3~~ PARTS 1 TO 3, 5, AND 6 of this article 280 are repealed, effective ~~September 1, 2021~~ SEPTEMBER 1, 2030. Before the repeal, the board and the regulation of the practice of pharmacy pursuant to ~~parts 1 to 3~~ PARTS 1 TO 3, 5, AND 6 of this article 280 ~~including the regulation of the practice as a pharmacy technician,~~ are scheduled for

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

review in accordance with section 24-34-104.

SECTION 2. In Colorado Revised Statutes, 24-34-104, **repeal** (21)(a)(II); and **add** (31)(a)(VI) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (21) (a) The following agencies, functions, or both, will repeal on September 1, 2021:

(II) ~~The state board of pharmacy and the regulation of the practice of pharmacy, including the regulation of the practice as a pharmacy technician, by the department of regulatory agencies through the division of professions and occupations in accordance with parts 1 to 3 of article 280 of title 12;~~

(31) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2030:

(VI) THE STATE BOARD OF PHARMACY AND THE REGULATION OF THE PRACTICE OF PHARMACY IN ACCORDANCE WITH PARTS 1 TO 3, 5, AND 6 OF ARTICLE 280 OF TITLE 12.

SECTION 3. In Colorado Revised Statutes, 12-280-103, **amend** (3), (4), (27), (32)(a) introductory portion, (38.5)(a)(V), (38.5)(a)(VI), (39)(a), (39)(d), (40), (43), (48), (54)(b)(III), (54)(b)(XI), and (55); **repeal** (9), (34), (37), (54)(b)(IX), and (54)(b)(XII); and **add** (9.7), (15.5), (28.5), (35.5), (38.5)(a)(VII), (38.5)(a)(VIII), (39)(f), (39)(g), (39)(h), (39)(i), (39)(j), (39)(k), (46.5), (52.5), and (54)(b)(XVI) as follows:

12-280-103. Definitions - rules. As used in this article 280, unless the context otherwise requires or the term is otherwise defined in another part of this article 280:

(3) ~~"Anabolic steroid" has the same meaning as set forth in section 18-18-102 (3)~~ "APPROVED TREATMENT FACILITY" MEANS AN APPROVED PRIVATE OR PUBLIC TREATMENT FACILITY, AS DESCRIBED IN SECTION 27-81-102 (2) AND (3) THAT ADHERES TO THE STANDARDS SET FORTH IN SECTION 27-81-106.

(4) ~~"Authorized distributor of record" means a wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection (4), an ongoing relationship is deemed to exist between a wholesaler and a manufacturer when the wholesaler, including any affiliated group of the wholesaler as defined in section 1504 of the federal "Internal Revenue Code of 1986", as amended, complies with the following:~~

~~(a) The wholesaler has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and~~

~~(b) The wholesaler is listed on the manufacturer's current list of authorized distributors of record, which list is updated by the manufacturer on no less than a monthly basis~~ "BEHAVIORAL HEALTH ENTITY" MEANS A BEHAVIORAL HEALTH ENTITY, AS DEFINED IN SECTION 25-27.6-102 (6), LICENSED PURSUANT TO ARTICLE 27.6 OF TITLE 25.

(9) ~~"Chain pharmacy warehouse" means a physical location for prescription drugs that serves as a central warehouse and performs intracompany sales or transfers of prescription drugs to a group of chain pharmacies or other chain pharmacy warehouses that are under common ownership or control. Notwithstanding any other provision of this article 280, a chain pharmacy warehouse receiving distributions on behalf of, or making distributions to, an intracompany pharmacy need not be an authorized distributor of record to be part of the normal distribution channel.~~

(9.7) "COMMUNITY MENTAL HEALTH CLINIC" HAS THE SAME MEANING AS SET FORTH IN SECTION 25-27.6-102 (9).

(15.5) "DQSA" MEANS THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB.L. 113-54, AS AMENDED.

(27) ~~"Manufacturer's exclusive distributor" means a person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. To be considered part of the normal distribution channel, as defined in section 12-280-301 (6), a manufacturer's exclusive distributor~~

~~shall be an authorized distributor of record~~ "MANUFACTURER" OR "MANUFACTURING DRUG OUTLET" MEANS A PERSON WHO MANUFACTURES DRUGS AND INCLUDES A RESIDENT 503B OUTSOURCING FACILITY.

(28.5) "NONRESIDENT 503B OUTSOURCING FACILITY" MEANS A FACILITY THAT IS REGISTERED BY THE FDA, THAT IS LOCATED OUTSIDE THE STATE, AND THAT DISTRIBUTES COMPOUNDED DRUGS INTO THE STATE WITHOUT A PRESCRIPTION ORDER.

(32) "Other outlet" means:

(a) A hospital that does not operate a registered pharmacy, a rural health clinic, a federally qualified health center, as defined in the federal "Social Security Act", 42 U.S.C. sec. 1395x (aa)(4), a family planning clinic, an acute treatment unit licensed by the department of public health and environment, a school, a jail, a county or district public health agency, a community health clinic, A COMMUNITY MENTAL HEALTH CLINIC, A BEHAVIORAL HEALTH ENTITY, AN APPROVED TREATMENT FACILITY, a university, or a college that:

(34) ~~"Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication-related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health-care professionals to attain the desired outcome. This function includes efforts to prevent, detect, and resolve medication-related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority, except that a pharmacist may prescribe only over-the-counter medications to a recipient under the "Colorado Medical Assistance Act" as authorized pursuant to section 25.5-5-322 or pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601 (1)(b).~~

(35.5) "PHARMACIST CARE SERVICES" MEANS PATIENT CARE ACTIVITIES PROVIDED BY A PHARMACIST, WITH OR WITHOUT DISPENSING A DRUG, THAT ARE INTENDED TO ACHIEVE OUTCOMES RELATED TO CURING OR

PREVENTING DISEASE, ELIMINATING OR REDUCING A PATIENT'S SYMPTOMS, OR ARRESTING OR SLOWING THE PROCESS OF A DISEASE. "PHARMACIST CARE SERVICES" INCLUDES EFFORTS TO PREVENT, DETECT, AND RESOLVE MEDICATION-RELATED PROBLEMS.

(37) ~~"Pharmacy buying cooperative warehouse" means a permanent physical location that acts as a central warehouse for prescription drugs and from which sales of prescription drugs are made to an exclusive group of pharmacies that are members or member owners of the buying cooperative operating the warehouse.~~

(38.5) (a) "Practice as a pharmacy technician" means engaging in any of the following activities involved in the practice of pharmacy, under the supervision and delegation of a supervising pharmacist:

(V) Transferring prescriptions; ~~and~~

(VI) ~~Other activities as authorized and defined by the board by rule~~ GATHERING, DOCUMENTING, AND MAINTAINING PROPER CLINICAL AND NONCLINICAL INFORMATION FROM PATIENTS;

(VII) REPLENISHING AUTOMATED DISPENSING DEVICES WITHOUT THE NEED FOR PHARMACIST VERIFICATION AS LONG AS THE PHARMACY TECHNICIAN USES BAR CODE TECHNOLOGY THAT CHECKS THE ACCURACY OF THE MEDICATION OR A SECOND PHARMACY TECHNICIAN PERFORMS THE VERIFICATION; AND

(VIII) OTHER ACTIVITIES AS AUTHORIZED AND DEFINED BY THE BOARD BY RULE.

(39) "Practice of pharmacy" means:

(a) The interpretation, evaluation, implementation, and dispensing of orders; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; THE provision of patient counseling; and the provision of those acts or services necessary to provide ~~pharmaceutical~~ PHARMACIST care SERVICES in all areas of patient care;

(d) The dispensing of chronic maintenance drugs pursuant to section

12-280-125.5 and board rules adopted in accordance with that section; ~~and~~

(f) PROVIDING CARE TO PATIENTS PURSUANT TO A COLLABORATIVE PHARMACY PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601;

(g) EXERCISING INDEPENDENT PRESCRIPTIVE AUTHORITY:

(I) AS AUTHORIZED PURSUANT TO SECTION 25.5-5-322, ONLY WITH REGARD TO OVER-THE-COUNTER MEDICATIONS PRESCRIBED TO RECIPIENTS UNDER THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5;

(II) IN ACCORDANCE WITH A COLLABORATIVE PHARMACY PRACTICE AGREEMENT AS DEFINED IN SECTION 12-280-601 (1)(b);

(III) AS AUTHORIZED PURSUANT TO SECTIONS 12-30-110 AND 12-280-123 (3) REGARDING OPIATE ANTAGONISTS; OR

(IV) FOR DRUGS THAT ARE NOT CONTROLLED SUBSTANCES, DRUG CATEGORIES, OR DEVICES THAT ARE PRESCRIBED IN ACCORDANCE WITH THE PRODUCT'S FDA-APPROVED LABELING AND TO PATIENTS WHO ARE AT LEAST TWELVE YEARS OF AGE AND THAT ARE LIMITED TO CONDITIONS THAT:

(A) DO NOT REQUIRE A NEW DIAGNOSIS;

(B) ARE MINOR AND GENERALLY SELF-LIMITING; OR

(C) HAVE A TEST THAT IS USED TO GUIDE DIAGNOSIS OR CLINICAL DECISION-MAKING AND IS WAIVED UNDER THE FEDERAL "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988", PUB.L. 100-578, AS AMENDED;

(h) ORDERING AND EVALUATING LABORATORY TESTS AS RELATED TO MEDICATION THERAPY;

(i) PERFORMING LIMITED PHYSICAL ASSESSMENTS COMMENSURATE WITH EDUCATION AND TRAINING;

(j) PERFORMING OTHER TASKS DELEGATED BY A LICENSED PHYSICIAN; AND

(k) PROVIDING TREATMENT THAT IS BASED ON NATIONAL, EVIDENCE-BASED, PUBLISHED GUIDANCE.

(40) "Practitioner" means a person authorized by law to prescribe any drug or device, acting within the scope of the authority, including a pharmacist who is participating within the parameters of a statewide drug therapy protocol pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601 (1)(b), ~~or~~ prescribing over-the-counter medications pursuant to section 25.5-5-322, OR PRESCRIBING AN OPIATE ANTAGONIST PURSUANT TO SECTIONS 12-30-110 AND 12-280-123 (3).

(43) "Prescription drug outlet" or "pharmacy" means any pharmacy outlet registered pursuant to this article 280 where prescriptions are compounded and dispensed. "Prescription drug outlet" includes, without limitation, a ~~compounding prescription drug outlet registered pursuant to section 12-280-119 (9) or~~ specialized prescription drug outlet registered pursuant to section 12-280-119 (11).

(46.5) "RESIDENT 503B OUTSOURCING FACILITY" MEANS A FACILITY THAT IS REGISTERED BY THE FDA, THAT IS LOCATED IN THE STATE, AND THAT DISTRIBUTES COMPOUNDED DRUGS WITHIN THE STATE.

(48) "Satellite" means an area outside the prescription drug outlet where ~~pharmaceutical care and~~ PHARMACIST CARE services are provided and that is in the same location.

(52.5) "THIRD-PARTY LOGISTICS PROVIDER" MEANS A PERSON THAT CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF A MANUFACTURER BUT DOES NOT TAKE TITLE TO A PRESCRIPTION DRUG OR HAVE GENERAL RESPONSIBILITY TO DIRECT THE PRESCRIPTION DRUG'S SALE OR DISPOSITION.

(54) (b) "Wholesale distribution" does not include:

(III) The sale or transfer of a PRESCRIPTION drug THAT IS NOT COMPOUNDED OR PREPACKAGED BY THE SELLING OR TRANSFERRING PHARMACY, EXCEPT AS ALLOWED PURSUANT TO SECTION 12-280-120 (15)(b), for medical reasons by ~~a retail~~ AN IN-STATE OR UNREGISTERED NONRESIDENT pharmacy to ~~another retail~~ A SEPARATE IN-STATE pharmacy

UNDER COMMON OWNERSHIP WITH THE SELLING OR TRANSFERRING IN-STATE OR UNREGISTERED NONRESIDENT PHARMACY to alleviate a temporary shortage;

(IX) ~~The direct sale, purchase, distribution, trade, or transfer of a prescription drug from a manufacturer to an authorized distributor of record to one additional authorized distributor of record but only if an authorized distributor of record that purchases a prescription drug from an authorized distributor of record that purchased the prescription drug directly from the manufacturer:~~

~~(A) Provides the supplying authorized distributor of record with a verifiable statement that the product is unavailable from the manufacturer; and~~

~~(B) Receives a verifiable statement from the supplying authorized distributor of record that the product was purchased directly from the manufacturer;~~

(XI) The sale or transfer from a retail pharmacy ~~or chain pharmacy warehouse~~ of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor;

(XII) ~~The sale or transfer of compounded drugs compounded by a retail pharmacy as defined in subsection (10) of this section and as authorized by section 12-280-120 (6)(b);~~

(XVI) THE SALE, PURCHASE, OR TRADE OF A DRUG OR AN OFFER TO SELL, PURCHASE, OR TRADE A DRUG BY A CHARITABLE ORGANIZATION DESCRIBED IN SECTION 501 (c)(3) OF THE FEDERAL "INTERNAL REVENUE CODE OF 1986", AS AMENDED, TO A NONPROFIT AFFILIATE OF THE ORGANIZATION TO THE EXTENT OTHERWISE PERMITTED BY LAW.

(55) "Wholesaler" means a person engaged in the wholesale distribution of prescription drugs to persons, other than consumers, ~~who are entitled~~ THAT ARE AUTHORIZED BY LAW to possess prescription drugs. ~~including: Repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug~~

~~traders; pharmacy buying cooperative warehouses; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.~~

SECTION 4. In Colorado Revised Statutes, 12-280-105, **amend** (1)(a), (1)(b), and (1)(c)(II) as follows:

12-280-105. Membership of board - removal - compensation - meetings - repeal. (1) (a) (I) The board is composed of five licensed pharmacists, each having at least five years' experience in this state and actively engaged in the practice of pharmacy in this state, and two nonpharmacists who have no financial interest in the practice of pharmacy.

(II) OF THE LICENSED PHARMACIST MEMBERS OF THE BOARD, ONE MUST BE ENGAGED IN PRACTICE IN A HOSPITAL SETTING, ONE MUST BE ENGAGED IN PRACTICE IN A CHAIN PHARMACY, AND ONE MUST BE ENGAGED IN PRACTICE IN AN INDEPENDENT PHARMACY.

(b) (I) The governor shall make all appointments to the board in accordance with this section.

(II) (A) FOR THE LICENSED PHARMACIST MEMBERS OF THE BOARD WHOSE TERMS EXPIRE ON JULY 1, 2021, AND JULY 1, 2022, THE GOVERNOR SHALL APPOINT LICENSED PHARMACIST MEMBERS THAT SATISFY THE REQUIREMENTS OF SUBSECTION (1)(a)(II) OF THIS SECTION.

(B) THIS SUBSECTION (1)(b)(II) IS REPEALED, EFFECTIVE DECEMBER 31, 2022.

(c) For purposes of achieving a balance in the membership on the board, the governor shall consider:

(II) The type of practice of the appointee so that various types of practices are represented on the board AND SO THAT THE LICENSED PHARMACIST MEMBERS OF THE BOARD SATISFY THE REQUIREMENTS OF SUBSECTION (1)(a)(II) OF THIS SECTION.

SECTION 5. In Colorado Revised Statutes, 12-280-106, **amend** (1)(a)(I)(B) and (2)(c) as follows:

12-280-106. Veterinary pharmaceutical advisory committee - creation - appointments - rules - repeal. (1) (a) (I) There is created in the department the veterinary pharmaceutical advisory committee comprised of three members, each appointed by the state veterinarian who serves under the commissioner of agriculture pursuant to section 35-50-104 as follows:

(B) One member who is either a ~~licensed pharmaceutical~~ wholesaler REGISTERED PURSUANT TO PART 3 OF THIS ARTICLE 280 engaged in the distribution of animal drugs, having at least five years' experience in this state, in good standing, and actively engaged in the practice of wholesale pharmacy or a licensed veterinarian, having at least five years' experience in this state, in good standing, and actively engaged in the practice of veterinary medicine, but who is not both a ~~pharmaceutical~~ wholesaler and a veterinarian; and

(2) (c) The board shall adopt the advisory committee's recommendation on a referred matter unless the board determines that there exists material and substantial evidence or information related to the matter that warrants a resolution of the matter that is distinct from the advisory committee's recommendation. ~~If the board deviates from the advisory committee's recommendation, the board shall make a record of the reasons for the deviation.~~

SECTION 6. In Colorado Revised Statutes, 12-280-108, **amend** (1)(a) and (1)(j); and **add** (1)(k) as follows:

12-280-108. Powers and duties - rules. (1) The board shall:

(a) (I) Inspect, or direct inspectors who are licensed pharmacists to inspect, all outlets and investigate violations of this article 280.

(II) THE BOARD'S AUTHORITY UNDER THIS SUBSECTION (1)(a) TO INSPECT ALL OUTLETS INCLUDES THE AUTHORITY, AFTER CONDUCTING A RISK-BASED ASSESSMENT, AS DEFINED BY THE BOARD BY RULE, TO INSPECT AN OUT-OF-STATE PHARMACY, A NONRESIDENT 503B OUTSOURCING FACILITY, OR AN OUT-OF-STATE WHOLESALER.

(j) Review and approve or reject applications for participation in the pharmacy peer health assistance ~~diversion~~ program pursuant to part 2 of this article 280 and perform any other functions that were performed by the

rehabilitation evaluation committee prior to its repeal;

(k) SEND A QUARTERLY ELECTRONIC NEWSLETTER TO ALL LICENSEES BY E-MAIL THAT DETAILS CHANGES IN STATE LAW THAT AFFECT OR ARE PERTINENT TO THE PRACTICE OF PHARMACY.

SECTION 7. In Colorado Revised Statutes, **amend** 12-280-111 as follows:

12-280-111. Malpractice claims information - not public - exception. ~~(1) Each insurance company licensed to do business in this state and engaged in the writing of malpractice insurance for licensed pharmacists and pharmacies, and each pharmacist or pharmacy that self-insures, shall send to the board, in the form prescribed by the board, information relating to each malpractice claim against a licensed pharmacist that is settled or in which judgment is rendered against the insured.~~

~~(2) The insurance company or self-insured pharmacist or pharmacy shall provide information relating to each malpractice claim as is deemed necessary by the board to conduct a further investigation and hearing.~~

~~(3)~~ Information relating to each malpractice claim provided by insurance companies or self-insured pharmacists or pharmacies PURSUANT TO SECTION 10-1-125.3 is exempt from the provisions of any law requiring that the proceedings of the board be conducted publicly or that the minutes or records of the board be open to public inspection unless the board takes final disciplinary action. The board may use the information in any formal hearing involving a licensee or registrant.

SECTION 8. In Colorado Revised Statutes, 12-280-118, **amend** (5)(a)(I) and (5)(a)(II) as follows:

12-280-118. Prescription drug outlet under charge of pharmacist - rules. (5) (a) Except as specified in subsection (5)(b) of this section, the pharmacist responsible for the prescription order or chart order may delegate the following tasks to the following individuals if, in the pharmacist's professional judgment, the delegation is appropriate:

(I) Specific tasks, excluding tasks described in section 12-280-103 (38.5)(a), ~~but which tasks may include delivery and proper and safe storage~~

~~of drugs or devices,~~ to ancillary personnel, other than a pharmacist or pharmacy intern, who are under the pharmacist's supervision, WHICH TASKS MAY INCLUDE:

(A) CASHIER TRANSACTIONS;

(B) MEDICATION SHIPPING AND HANDLING;

(C) MEDICATION TRANSPORTATION;

(D) RECORD KEEPING;

(E) TELEPHONE OR COMMUNICATION TRIAGE; OR

(F) INVENTORY MANAGEMENT; or

(II) Specific tasks described in section 12-280-103 (38.5)(a) or in board rules adopted pursuant to section 12-280-103 ~~(38.5)(a)(VI)~~ (38.5)(a)(VIII) to a pharmacy technician who is under the pharmacist's supervision.

SECTION 9. In Colorado Revised Statutes, 12-280-119, **amend** (7) and (11); and **repeal** (9) as follows:

12-280-119. Registration of facilities - rules. (7) A separate registration is required under this section for any area outside the outlet that is not a satellite where ~~pharmaceutical~~ PHARMACIST care ~~and~~ services are provided and for any area outside the outlet that is under different ownership from the outlet.

~~(9) (a) Subject to subsection (9)(b) of this section, a prescription drug outlet may register as a compounding prescription drug outlet.~~

~~(b) The board shall not register a facility as a compounding prescription drug outlet unless:~~

~~(I) The facility has been accredited by a board-approved compounding accreditation entity to be within acceptable parameters to compound more than ten percent of the facility's total sales; and~~

~~(II) Ownership of the facility is vested solely in a pharmacist.~~

~~(c) To be approved by the board to accredit a compounding prescription drug outlet, a compounding accreditation entity shall be, at a minimum, a scientific organization with expertise in compounding medications.~~

(11) A prescription drug outlet may register as a specialized prescription drug outlet if it engages in the compounding, dispensing, and delivery of drugs and devices to, or the provision of ~~pharmaceutical~~ PHARMACIST care SERVICES to residents of, a long-term care facility. The board shall adopt rules as necessary to implement this subsection (11).

SECTION 10. In Colorado Revised Statutes, 12-280-120, **amend** (6)(b), (10), and (15)(b) introductory portion; and **repeal** (15)(a) as follows:

12-280-120. Compounding - dispensing - sale of drugs and devices - rules - definition. (6) (b) (I) ~~The board shall promulgate rules authorizing~~ A prescription drug outlet located in this state ~~to~~ MAY compound AND DISTRIBUTE drugs ~~for office use by a practitioner or for use by a hospital located in this state. The rules must limit the amount of drugs a prescription drug outlet may compound and distribute to a practitioner or hospital~~ FOR VETERINARY USE pursuant to ~~this subsection (6)(b) to no more than~~ SECTION 12-280-121, BUT THE AMOUNT OF DRUGS THE PRESCRIPTION DRUG OUTLET MAY COMPOUND AND DISTRIBUTE FOR VETERINARY USE MUST NOT EXCEED ten percent of the total number of drug dosage units dispensed and distributed on an annual basis by the outlet.

(II) ~~(A) The ten percent limitation set forth in subsection (6)(b)(I) of this section applies to a compounded drug for veterinary use that a prescription drug outlet distributes in Colorado.~~

~~(B) For purposes of this subsection (6)(b)(II)~~ AS USED IN THIS SUBSECTION (6)(b), a "prescription drug outlet" includes a nonresident pharmacy outlet registered or licensed pursuant to this article 280 where prescriptions are compounded and dispensed, but only if the nonresident pharmacy outlet has provided the board with a copy of the most recent inspection of the nonresident pharmacy outlet by the agency that regulates pharmaceuticals in the state of residence and a copy of the most recent inspection received from a board-approved third-party entity that inspects

pharmacy outlets, for which third-party inspection the nonresident pharmacy outlet shall obtain and pay for on an annual basis, and the board approves the inspection reports as satisfactorily demonstrating proof of compliance with the board's own inspection procedure and standards.

(10) (a) Any hospital employee or agent authorized by law to administer or dispense medications may dispense a ~~twenty-four-hour~~ SEVENTY-TWO-HOUR supply of drugs on the specific order of a practitioner to a registered emergency room patient.

(b) A HOSPITAL MAY DISPENSE A PRESCRIPTION DRUG PURSUANT TO A CHART ORDER FOR A HOSPITALIZED PATIENT FOR USE BY THE PATIENT DURING A TEMPORARY LEAVE FROM THE HOSPITAL OF LESS THAN SEVENTY-TWO HOURS IF THE PRESCRIPTION DRUG:

(I) IS LABELED IN ACCORDANCE WITH SECTION 12-280-124 (1) AND (2);

(II) IS ADMINISTERED BY AN AUTHORIZED PERSON;

(III) IS DISPENSED PURSUANT TO A CURRENT, ACTIVE ORDER; AND

(IV) IS LIMITED TO A SEVENTY-TWO-HOUR SUPPLY OR, IF THE TEMPORARY LEAVE IS FOR LESS THAN TWENTY-FOUR HOURS, THE QUANTITY THE PATIENT REQUIRES DURING THE TEMPORARY LEAVE.

(15) (a) ~~A compounding prescription drug outlet registered pursuant to section 12-280-119 (9) may dispense and distribute compounded drugs without limitation to practitioners or to prescription drug outlets under common ownership with the pharmacist who owns the compounding prescription drug outlet.~~

(b) The following may distribute ~~compounded and~~ prepackaged medications, without limitation, to pharmacies and other outlets under common ownership of the entity:

SECTION 11. In Colorado Revised Statutes, 12-280-121, **amend** (3), (4), and (6) as follows:

12-280-121. Compounding drugs for office use by a veterinarian

- rules - definitions. (3) A licensed veterinarian shall not administer or dispense a compounded drug maintained for office stock pursuant to this section or for office use pursuant to ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b) without a valid veterinarian-client-patient relationship in place at the time of administering the compounded drug to an animal patient or dispensing the compounded drug to a client.

(4) To compound and distribute a controlled substance pursuant to this section or ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b), a registered prescription drug outlet shall possess a valid manufacturing registration from the federal drug enforcement administration.

(6) The board may promulgate rules as necessary concerning compounded veterinary pharmaceuticals pursuant to this section and ~~section 12-280-120 (6)(b)(II)~~ SECTION 12-280-120 (6)(b).

SECTION 12. In Colorado Revised Statutes, 12-280-123, **amend** (3) as follows:

12-280-123. Prescription required - exception - prescribing and dispensing opiate antagonists - selling nonprescription syringes and needles. (3) A pharmacist may PRESCRIBE AND dispense an opiate antagonist in accordance with section 12-30-110.

SECTION 13. In Colorado Revised Statutes, 12-280-124, **amend** (1)(b) as follows:

12-280-124. Labeling - rules. (1) A prescription drug dispensed pursuant to an order must be labeled as follows:

(b) ~~(I) If the prescription is for an anabolic steroid, the purpose for which the anabolic steroid is being prescribed must appear on the label.~~

~~(II) If the prescription is for any drug other than an anabolic steroid~~ The symptom or purpose for which the drug is being prescribed must appear on the label, if, after being advised by the practitioner, the patient or the patient's authorized representative so requests. If the practitioner does not provide the symptom or purpose for which a drug is being prescribed, the pharmacist may fill the prescription order without contacting the practitioner, patient, or patient's representative. ~~unless the prescription is for~~

~~an anabolic steroid.~~

SECTION 14. In Colorado Revised Statutes, 12-280-125, **amend** (2)(a) introductory portion, (3)(b), and (5); and **add** (1)(a.5) as follows:

12-280-125. Substitution of prescribed drugs and biological products authorized - when - conditions. (1) (a.5) (I) A PHARMACIST FILLING A PRESCRIPTION ORDER FOR A SPECIFIC DRUG MAY SUBSTITUTE A DRUG IN THE SAME THERAPEUTIC CLASS AS LONG AS THE PATIENT AGREES TO THE SUBSTITUTION AND THE SUBSTITUTION IS MADE TO REPLACE A DRUG THAT IS ON BACK ORDER, TO ENSURE FORMULARY COMPLIANCE WITH THE PATIENT'S HEALTH INSURANCE PLAN, OR, IN THE CASE OF AN UNINSURED PATIENT, TO LOWER THE COST TO THE PATIENT FOR THE DRUG WHILE MAINTAINING SAFETY.

(II) THIS SUBSECTION (1)(a.5) DOES NOT AUTHORIZE:

(A) THE SUBSTITUTION OF BIOLOGICAL PRODUCTS, NARROW THERAPEUTIC INDEX DRUGS, OR PSYCHOTROPIC DRUGS; OR

(B) A SUBSTITUTION WHEN THE PRACTITIONER HAS INDICATED, IN THE MANNER DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE PHARMACIST SHALL NOT SUBSTITUTE A DRUG IN THE SAME THERAPEUTIC CLASS AS THE DRUG PRESCRIBED.

(2) (a) If, in the opinion of the practitioner, it is in the best interest of the patient that the pharmacist not substitute an equivalent drug, A DRUG IN THE SAME THERAPEUTIC CLASS, or AN interchangeable biological product for the specific drug or biological product ~~he or she~~ THE PRACTITIONER prescribed, the practitioner may convey this information to the pharmacist in any of the following manners:

(3) (b) The pharmacist is not required to communicate a substitution to ~~institutionalized~~ patients IN AN INPATIENT SETTING OR AN OUTPATIENT INFUSION CENTER.

(5) If a prescription drug outlet does not have in stock the prescribed drug or biological product and the only equivalent drug, DRUG IN THE SAME THERAPEUTIC CLASS, or interchangeable biological product in stock is higher priced, the pharmacist, with the consent of the purchaser, may

substitute the higher priced drug or interchangeable biological product. This subsection (5) applies only to a prescription drug outlet located in a town, as defined in section 31-1-101 (13).

SECTION 15. In Colorado Revised Statutes, **add** 12-280-125.3 as follows:

12-280-125.3. Pharmacists' authority - minor prescription adaptions. (1) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION, A PHARMACIST WHO IS ACTING IN GOOD FAITH AND IS USING PROFESSIONAL JUDGMENT AND EXERCISING REASONABLE CARE MAY MAKE THE FOLLOWING MINOR ADAPTIONS TO AN ORDER IF THE PHARMACIST HAS THE INFORMED CONSENT OF THE PATIENT FOR WHOM THE PRESCRIPTION WAS PROVIDED:

(a) A CHANGE IN THE PRESCRIBED DOSAGE FORM OR DIRECTIONS FOR USE OF THE PRESCRIPTION DRUG IF THE CHANGE ACHIEVES THE INTENT OF THE PRESCRIBING PRACTITIONER;

(b) A CHANGE IN THE PRESCRIBED QUANTITY OF THE PRESCRIPTION DRUG IF THE PRESCRIBED QUANTITY IS NOT A PACKAGE SIZE COMMERCIALLY AVAILABLE FROM THE MANUFACTURER;

(c) AN EXTENSION OF THE QUANTITY OF A MAINTENANCE DRUG FOR THE LIMITED QUANTITY NECESSARY TO ACHIEVE MEDICATION REFILL SYNCHRONIZATION FOR THE PATIENT; AND

(d) COMPLETION OF MISSING INFORMATION ON THE ORDER IF THERE IS SUFFICIENT EVIDENCE TO SUPPORT THE CHANGE.

(2) A PHARMACIST WHO ADAPTS AN ORDER IN ACCORDANCE WITH SUBSECTION (1) OF THIS SECTION SHALL DOCUMENT THE ADAPTION AND THE JUSTIFICATION FOR THE CHANGE IN THE PATIENT'S PHARMACY RECORD WITH THE ORIGINAL PRESCRIPTION AND SHALL NOTIFY THE PRESCRIBING PRACTITIONER OF THE ADAPTION.

(3) A PHARMACIST SHALL NOT ADAPT AN ORDER IF THE PRESCRIBING PRACTITIONER HAS WRITTEN "DO NOT ADAPT" ON THE PRESCRIPTION OR HAS OTHERWISE COMMUNICATED TO THE PHARMACIST THAT THE PRESCRIPTION MUST NOT BE ADAPTED.

SECTION 16. In Colorado Revised Statutes, 12-280-126, **amend** (1)(e); and **add** (1)(t) as follows:

12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee, certificant, or registrant:

(e) ~~Has a substance use disorder, as defined in section 27-81-102, or~~ Engages in the habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance, as defined in section 18-18-102 (5);

(t) HAS FAILED TO NOTIFY THE BOARD, IN WRITING AND WITHIN THIRTY DAYS AFTER A JUDGMENT OR SETTLEMENT IS ENTERED, OF A FINAL JUDGMENT BY A COURT OF COMPETENT JURISDICTION AGAINST THE LICENSEE OR REGISTRANT FOR MALPRACTICE IN THE PRACTICE OF PHARMACY OR A SETTLEMENT BY THE LICENSEE IN RESPONSE TO CHARGES OR ALLEGATIONS OF MALPRACTICE IN THE PRACTICE OF PHARMACY AND, IN THE CASE OF A JUDGMENT, HAS FAILED TO INCLUDE IN THE NOTICE THE NAME OF THE COURT, THE CASE NUMBER, AND THE NAMES OF ALL PARTIES TO THE ACTION;

SECTION 17. In Colorado Revised Statutes, 12-280-127, **amend** (6) as follows:

12-280-127. Disciplinary actions. (6) The board may send a letter of admonition ~~by certified mail~~ to a licensee, certificant, or registrant under the circumstances specified in and in accordance with section 12-20-404 (4). In the case of a complaint, the board may send a copy of the letter of admonition to the person making the complaint.

SECTION 18. In Colorado Revised Statutes, **add** 12-280-133.5 and 12-280-133.7 as follows:

12-280-133.5. Nonresident 503B outsourcing facility - registration - requirements - denial, revocation, or suspension - rules. (1) A NONRESIDENT 503B OUTSOURCING FACILITY SHALL NOT CONDUCT THE BUSINESS OF DISTRIBUTING COMPOUNDED PRESCRIPTION DRUGS IN THIS STATE WITHOUT FIRST REGISTERING WITH THE BOARD AS A NONRESIDENT

503B OUTSOURCING FACILITY. A NONRESIDENT 503B OUTSOURCING FACILITY SHALL APPLY FOR A NONRESIDENT 503B OUTSOURCING FACILITY REGISTRATION ON A FORM FURNISHED BY THE BOARD AND SHALL SUBMIT THE FOLLOWING TO THE BOARD WITH THE APPLICATION:

(a) PROOF THAT THE FACILITY IS ACTIVELY REGISTERED WITH THE FDA AS A 503B OUTSOURCING FACILITY AND IS ACTIVELY LICENSED, PERMITTED, OR REGISTERED IN THE STATE IN WHICH IT IS A RESIDENT;

(b) THE LOCATION, NAMES, AND TITLES OF ALL PRINCIPAL ENTITY OFFICERS AND THE NAME OF THE PHARMACIST IN CHARGE OF THE OPERATIONS OF THE FACILITY;

(c) VERIFICATION THAT THE FACILITY COMPLIES WITH ALL LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA AND FROM THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS LICENSED, PERMITTED, OR REGISTERED, AS WELL AS WITH ALL REQUESTS FOR INFORMATION MADE BY THE BOARD PURSUANT TO THIS SECTION;

(d) A COPY OF THE MOST RECENT INSPECTION REPORT RESULTING FROM AN INSPECTION CONDUCTED BY THE FDA; AND

(e) ANY OTHER INFORMATION THE BOARD DEEMS NECESSARY TO CARRY OUT THE PURPOSE OF THIS SECTION.

(2) A NONRESIDENT 503B OUTSOURCING FACILITY SHALL:

(a) MAINTAIN AT ALL TIMES A VALID, UNEXPIRED LICENSE, PERMIT, OR REGISTRATION TO OPERATE THE 503B OUTSOURCING FACILITY IN COMPLIANCE WITH THE LAWS OF THE STATE IN WHICH IT IS A RESIDENT; AND

(b) COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, OR THE DQSA OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT.

(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A NONRESIDENT 503B OUTSOURCING FACILITY REGISTRATION IF:

(a) THE FACILITY FAILS TO COMPLY WITH THIS SECTION OR WITH ANY RULE PROMULGATED BY THE BOARD;

(b) THE FDA HAS REVOKED OR REFUSED TO RENEW THE NONRESIDENT 503B OUTSOURCING FACILITY'S FDA REGISTRATION FOR FAILING TO COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, THE DQSA, OR FDA REGULATIONS IMPLEMENTING EITHER ACT OR THE FACILITY'S FDA REGISTRATION HAS EXPIRED OR IS NO LONGER ACTIVE; OR

(c) THE STATE IN WHICH THE NONRESIDENT 503B OUTSOURCING FACILITY RESIDES HAS REVOKED OR REFUSED TO RENEW THE FACILITY'S LICENSE, PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE LAWS OF THAT STATE OR THE FACILITY'S LICENSE, PERMIT, OR REGISTRATION IN ANOTHER STATE HAS EXPIRED OR IS NO LONGER ACTIVE.

(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

12-280-133.7. Third-party logistics providers - registration - denial, revocation, or suspension - rules. (1) A THIRD-PARTY LOGISTICS PROVIDER SHALL NOT CONDUCT BUSINESS IN THIS STATE WITHOUT FIRST REGISTERING WITH THE BOARD AS A THIRD-PARTY LOGISTICS PROVIDER. A THIRD-PARTY LOGISTICS PROVIDER SHALL APPLY FOR A REGISTRATION ON A FORM FURNISHED BY THE BOARD AND SHALL SUBMIT THE INFORMATION REQUIRED PURSUANT TO RULES ADOPTED BY THE BOARD. THE BOARD SHALL SPECIFY, BY RULE, THE INFORMATION A THIRD-PARTY LOGISTICS PROVIDER MUST SUBMIT WITH ITS APPLICATION FOR A REGISTRATION.

(2) A THIRD-PARTY LOGISTICS PROVIDER SHALL COMPLY WITH ALL LAWFUL DIRECTIONS AND REQUESTS FOR INFORMATION FROM THE FDA, THE REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH IT IS LICENSED, PERMITTED, OR REGISTERED, AND THE BOARD.

(3) THE BOARD MAY DENY, REVOKE, OR SUSPEND A THIRD-PARTY LOGISTICS PROVIDER REGISTRATION IF:

(a) THE THIRD-PARTY LOGISTICS PROVIDER FAILS TO COMPLY WITH THIS SECTION OR WITH ANY RULE PROMULGATED BY THE BOARD;

(b) THE FDA HAS REVOKED OR REFUSED TO RENEW THE THIRD-PARTY LOGISTICS PROVIDER'S FDA REGISTRATION FOR FAILING TO COMPLY WITH THE REQUIREMENTS OF THE "FEDERAL FOOD, DRUG, AND

COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ., AS AMENDED, OR THE DQSA OR WITH FDA REGULATIONS IMPLEMENTING EITHER ACT; OR

(c) THE STATE IN WHICH THE THIRD-PARTY LOGISTICS PROVIDER RESIDES HAS REVOKED OR REFUSED TO RENEW THE PROVIDER'S LICENSE, PERMIT, OR REGISTRATION FOR FAILING TO COMPLY WITH THE LAWS OF THAT STATE.

(4) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

SECTION 19. In Colorado Revised Statutes, 12-280-134, **add** (10) as follows:

12-280-134. Records. (10) THE BOARD SHALL ALLOW ELECTRONIC STORAGE OF RECORDS REQUIRED TO BE MAINTAINED PURSUANT TO THIS SECTION.

SECTION 20. In Colorado Revised Statutes, **add** 12-280-137 and 12-280-138 as follows:

12-280-137. Investigations of suspicious drugs. ALL PRESCRIPTION DRUG OUTLETS, MANUFACTURERS, REPACKAGERS, AND WHOLESALERS SHALL INVESTIGATE ANY SUSPECT PRODUCT, AS DEFINED IN THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA, AND SHALL USE DOCUMENTATION AND REPORTING PROCEDURES RELATING TO THE INVESTIGATION IN ACCORDANCE WITH THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

12-280-138. Patient counseling - pharmacists required to perform - patient may decline - rules. (1) (a) EXCEPT IN THE CIRCUMSTANCES DESCRIBED IN SUBSECTION (2) OF THIS SECTION, A PHARMACIST SHALL PROVIDE PATIENT COUNSELING ON NEW MEDICATION THERAPY AND, BASED ON THE PHARMACIST'S PROFESSIONAL JUDGMENT AND DUE DILIGENCE, MAY PROVIDE PATIENT COUNSELING FOR ANY OTHER PRESCRIPTION. IF THE PHARMACIST IS UNABLE TO PROVIDE PATIENT COUNSELING ORALLY DUE TO LANGUAGE BARRIERS, THE PHARMACIST MAY USE ALTERNATE MEANS TO PROVIDE THE PATIENT COUNSELING.

(b) (I) EXCEPT AS PROVIDED IN SUBSECTION (1)(b)(II) OF THIS

SECTION, ALL IN-STATE PHARMACIES MUST ENSURE THAT THEIR PHARMACISTS PROVIDE PATIENT COUNSELING IN ACCORDANCE WITH THIS SECTION.

(II) THIS SUBSECTION (1)(b) DOES NOT APPLY TO AN OTHER OUTLET.

(2) A PATIENT MAY DECLINE PATIENT COUNSELING OFFERED BY A PHARMACIST. A PHARMACIST SHALL DOCUMENT, IN THE FORM AND MANNER SPECIFIED IN BOARD RULES, WHEN A PATIENT DECLINES PATIENT COUNSELING.

(3) THE BOARD SHALL ADOPT RULES SPECIFYING:

(a) THE ALTERNATE MEANS BY WHICH PHARMACISTS MAY PROVIDE PATIENT COUNSELING WHEN LANGUAGE BARRIERS PRECLUDE PROVIDING PATIENT COUNSELING ORALLY; AND

(b) THE FORM AND MANNER FOR PHARMACISTS TO DOCUMENT WHEN A PATIENT DECLINES COUNSELING, WHICH RULES MUST SPECIFY A DOCUMENTATION PROCESS THAT IS SIMPLE AND ALLOWS THE DOCUMENTATION TO BE COMPLETED ELECTRONICALLY.

(4) THIS SECTION DOES NOT APPLY TO PHARMACISTS WHO DISPENSE PRESCRIPTION DRUGS TO PERSONS IN THE CUSTODY OF THE DEPARTMENT OF CORRECTIONS.

SECTION 21. In Colorado Revised Statutes, **amend** 12-280-201 as follows:

12-280-201. Legislative declaration. (1) The general assembly finds, determines, and declares that the creation of a pharmacy peer health assistance ~~diversion~~ program for those persons subject to the jurisdiction of the board will serve to safeguard the life, health, property, and public welfare of the people of this state. A pharmacy peer health assistance ~~diversion~~ program will help practitioners experiencing impaired practice due to psychiatric, psychological, or emotional problems; excessive alcohol or drug use; or alcohol or substance use disorders. The general assembly further declares that a pharmacy peer health assistance ~~diversion~~ program will protect the privacy and welfare of those persons who provide services and at the same time assist the board in carrying out its duties and

responsibilities to ensure that only qualified persons are allowed to engage in providing those services that are under the jurisdiction of the board.

(2) It is the intent of the general assembly that the pharmacy peer health assistance ~~diversion~~ program and its related procedures be utilized by the board in conjunction with, or as an alternative to, the use of disciplinary proceedings by the board, which proceedings are by their nature time-consuming and costly to the people of this state. The pharmacy peer health assistance ~~diversion~~ program is hereby established to alleviate the need for disciplinary proceedings, while at the same time providing safeguards that protect the public health, safety, and welfare. The general assembly further declares that it intends that the board will act to implement the provisions of this article 280.

SECTION 22. In Colorado Revised Statutes, 12-280-203, **amend** (2)(b) introductory portion as follows:

12-280-203. Pharmacy peer health assistance fund - rules. (2) (b) The board shall select one or more peer health assistance organizations as designated providers. To be eligible for designation by the board, a peer health assistance ~~diversion~~ program shall:

SECTION 23. In Colorado Revised Statutes, 12-280-204, **amend** (1), (2)(b), and (3) as follows:

12-280-204. Eligibility - participants. (1) Any licensee may apply to the board for participation in a qualified peer health assistance ~~diversion~~ program.

(2) In order to be eligible for participation, a licensee shall:

(b) After a full explanation of the operation and requirements of the peer health assistance ~~diversion~~ program, agree to voluntarily participate in the program and agree in writing to participate in the program of the peer health assistance organization designated by the board.

(3) Notwithstanding the provisions of this section, the board may summarily suspend the license of any licensee who is referred to a peer health assistance ~~diversion~~ program by the board and who fails to attend or to complete the program. If the board summarily suspends the license, the

board shall schedule a hearing on the suspension, which shall be conducted in accordance with section 24-4-105.

SECTION 24. In Colorado Revised Statutes, **amend** 12-280-205 as follows:

12-280-205. Liability. Nothing in this part 2 creates any liability of the board, members of the board, or the state of Colorado for the actions of the board in making awards to pharmacy peer health assistance organizations or in designating licensees to participate in the programs of pharmacy peer health assistance organizations. No civil action may be brought or maintained against the board, its members, or the state for an injury alleged to have been the result of an act or omission of a licensee participating in or referred to a state-funded program provided by a pharmacy peer health assistance organization. However, the state remains liable under the "Colorado Governmental Immunity Act", article 10 of title 24, if an injury alleged to have been the result of an act or omission of a licensee participating in or referred to a state-funded peer health assistance ~~diversion~~ program occurred while the licensee was performing duties as an employee of the state.

SECTION 25. In Colorado Revised Statutes, 12-280-301, **amend** (3) and (7); **repeal** (1), (4), (6), and (8); and **add** (7.5) as follows:

12-280-301. Definitions. As used in this part 3, unless the context otherwise requires:

(1) ~~"Authentication" means the process of affirmatively verifying that each transaction listed on a pedigree has occurred before any wholesale distribution of a prescription drug occurs.~~

(3) "Designated representative" means a person authorized by a ~~licensed~~ REGISTERED wholesaler to act as a representative for the wholesaler.

(4) ~~"Drop shipment" means the sale by a manufacturer of the manufacturer's prescription drug, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor to a wholesaler whereby the wholesaler takes title to, but not possession of, the prescription drug and the wholesaler invoices the board-registered outlet or practitioner~~

~~authorized by law to prescribe the prescription drug and the board-registered outlet or the practitioner authorized by law to prescribe the prescription drug receives delivery of the prescription drug directly from the manufacturer of the drug, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.~~

~~(6) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly or by drop shipment from a manufacturer of the prescription drug to:~~

~~(a) (I) A wholesaler to a pharmacy to a patient or other designated persons authorized by law to dispense or administer a prescription drug to a patient;~~

~~(II) A wholesaler to a chain pharmacy warehouse to their intracompany pharmacies to a patient;~~

~~(III) A chain pharmacy warehouse to its intracompany pharmacies to a patient; or~~

~~(IV) A pharmacy to a patient; or~~

~~(b) A manufacturer's colicensed partner, third-party logistics provider, or exclusive distributor to a wholesaler to a pharmacy to a patient or other designated persons authorized by law to dispense or administer the prescription drug to a patient; or~~

~~(c) A manufacturer's colicensed partner, or that manufacturer's third-party logistics provider, or exclusive distributor to a wholesaler to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer the prescription drug to a patient; or~~

~~(d) A wholesaler to a pharmacy buying cooperative warehouse to a pharmacy that is a member or member owner of the cooperative to a patient or other designated person authorized by law to dispense or administer the prescription drug to a patient.~~

(7) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug

~~that leaves the normal distribution channel~~ IN ACCORDANCE WITH THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

(7.5) "PRESCRIPTION DRUG" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-103 (42); EXCEPT THAT "PRESCRIPTION DRUG" EXCLUDES ANY DRUG SPECIFICALLY EXEMPTED UNDER THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

(8) ~~"Third-party logistics provider" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a prescription drug or have general responsibility to direct the prescription drug's sale or disposition.~~

SECTION 26. In Colorado Revised Statutes, **repeal** 12-280-302.

SECTION 27. In Colorado Revised Statutes, 12-280-303, **amend** (1), (2)(b), (2)(c), (3)(a) introductory portion, (3)(a)(VI), (3)(b), (4), (5) introductory portion, (5)(f), and (6) as follows:

12-280-303. Wholesaler registration requirements - rules. (1) ~~(a)~~ A wholesaler that resides in this state must ~~be licensed by~~ REGISTER WITH the board BEFORE ENGAGING IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN THIS STATE. A wholesaler that does not reside in this state must be ~~licensed~~ REGISTERED in this state prior to engaging in the wholesale distribution of prescription drugs in this state. ~~The board shall exempt a manufacturer and that manufacturer's third-party logistics providers to the extent involving that manufacturer's drugs under contract from any licensing qualifications and other requirements, including the requirements in subsections (3)(a)(VI) and (3)(a)(VII) of this section, subsections (4) to (6) of this section, and section 12-280-304, to the extent the requirements are not required by federal law or regulation, unless the particular requirements are deemed necessary and appropriate following rule-making by the board.~~

~~(b) A manufacturer's exclusive distributor and pharmacy buying cooperative warehouse must be licensed by the board as a wholesaler pursuant to this part 3. A third-party logistics provider must be licensed by the board as a wholesale distributor pursuant to this part 3.~~

(2) (b) An applicant for a ~~license~~ REGISTRATION shall pay any fee required by the accreditation body or the board and comply with any rules promulgated by the board.

(c) The board shall not issue or renew a ~~license~~ REGISTRATION to a wholesaler who does not comply with this part 3.

(3) (a) An applicant for a wholesaler ~~license~~ REGISTRATION shall provide to the board the following information, and any other information deemed appropriate by the board, on a form provided by the board:

(VI) A list of the licenses, ~~and~~ REGISTRATIONS, OR permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs; and

(b) A ~~licensee~~ REGISTRANT shall complete and return a form approved by the board at each renewal period. The board may suspend or revoke the ~~license~~ REGISTRATION of a wholesaler if the board determines that the wholesaler no longer qualifies for a ~~license~~ REGISTRATION.

(4) Prior to issuing a wholesaler ~~license~~ REGISTRATION to an applicant, the board, the regulatory oversight body from another state, or a board-approved accreditation body may conduct a physical inspection of the facility at the business address provided by the applicant. Nothing in this subsection (4) ~~shall preclude~~ PRECLUDES the board from inspecting a wholesaler.

(5) The designated representative of an applicant for a wholesaler ~~license~~ REGISTRATION shall:

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one ~~licensed~~ REGISTERED wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue Code of 1986", as amended;

(6) A wholesaler shall obtain a ~~license~~ REGISTRATION for each facility it uses for the distribution of prescription drugs.

SECTION 28. In Colorado Revised Statutes, 12-280-305, **repeal**

(1) and (4) as follows:

12-280-305. Restrictions on transactions. (1) ~~A wholesaler shall accept prescription drug returns or exchanges from a pharmacy or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. The receiving wholesale distributor shall distribute returns or exchanges of expired, damaged, recalled, or otherwise unsaleable pharmaceutical product only to the original manufacturer or to a third-party returns processor. The returns or exchanges of prescription drugs, saleable or unsaleable, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirements of section 12-280-306 so long as the drugs are exempt from the pedigree requirement of the federal food and drug administration's currently applicable "Prescription Drug Marketing Act of 1987" guidance. The pharmacies, chain pharmacy warehouses, and pharmacy buying cooperative warehouses are responsible for ensuring that the prescription drugs returned are what they purport to be and shall ensure that those returned prescription drugs were stored under proper conditions since their receipt. Wholesalers are responsible for policing their returns process and helping to ensure that their operations are secure and do not permit the entry of adulterated or counterfeit product. A pharmacist shall not knowingly return a medication that is not what it purports to be.~~

(4) ~~A manufacturer or wholesaler shall not accept payment for, or allow the use of, a person's or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. An account established for the purchase of prescription drugs must bear the name of the licensee. This subsection (4) does not apply to standard ordering and purchasing business practices between a chain pharmacy warehouse, a wholesaler, and a manufacturer.~~

SECTION 29. In Colorado Revised Statutes, **repeal and reenact, with amendments,** 12-280-306 as follows:

12-280-306. Records - pedigree - compliance with DQSA. A WHOLESALER SHALL ESTABLISH AND MAINTAIN INVENTORIES AND RECORDS OF ALL TRANSACTIONS REGARDING THE RECEIPT AND DISTRIBUTION OR OTHER DISPOSITION OF PRESCRIPTION DRUGS. THE RECORDS MUST INCLUDE

THE PEDIGREE FOR EACH WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG AS REQUIRED PURSUANT TO THE DQSA AND ANY FEDERAL REGULATIONS IMPLEMENTING THE DQSA.

SECTION 30. In Colorado Revised Statutes, 12-280-403, **amend** (2)(b) introductory portion as follows:

12-280-403. Prescription drug use monitoring program - registration required. (2) (b) When registering with the program or at any time thereafter, a practitioner ~~or pharmacist~~ may authorize up to three designees to access the program under section 12-280-404 (3)(b) OR (3)(d) ~~or (3)(f), as applicable,~~ on behalf of the practitioner, ~~or~~ AND A pharmacist MAY AUTHORIZE UP TO SIX DESIGNEES TO ACCESS THE PROGRAM UNDER SECTION 12-280-404 (3)(f), if:

SECTION 31. In Colorado Revised Statutes, 12-30-110, **amend** (1)(a) introductory portion, (2)(a), (3) introductory portion, (4)(a), and (7)(h) as follows:

12-30-110. Prescribing or dispensing opiate antagonists - authorized recipients - definitions. (1) (a) A prescriber may prescribe or dispense, directly or in accordance with standing orders and protocols, ~~and a pharmacist may dispense, pursuant to an order or standing orders and protocols,~~ an opiate antagonist to:

(2) (a) A prescriber who prescribes or dispenses ~~or a pharmacist who dispenses,~~ an opiate antagonist pursuant to this section is strongly encouraged to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including instruction concerning risk factors for overdose, recognizing an overdose, calling emergency medical services, rescue breathing, and administering an opiate antagonist.

(3) ~~Neither~~ A prescriber described in ~~subsection (7)(h)(I)~~ SUBSECTION (7)(h) of this section ~~nor a pharmacist engages~~ DOES NOT ENGAGE in unprofessional conduct OR IS NOT SUBJECT TO DISCIPLINE pursuant to section 12-240-121, ***12-255-120***, or 12-280-126, ~~respectively, and a prescriber described in subsection (7)(h)(II) of this section does not engage in conduct that is grounds for discipline pursuant to section 12-255-120~~ AS APPLICABLE, if the prescriber issues standing orders and protocols regarding opiate antagonists or prescribes or dispenses, ~~or the~~

~~pharmacist dispenses,~~ pursuant to an order or standing orders and protocols, an opiate antagonist in a good-faith effort to assist:

(4) (a) A prescriber ~~or pharmacist~~ who prescribes or dispenses an opiate antagonist in accordance with this section is not subject to civil liability or criminal prosecution, as specified in sections 13-21-108.7 (4) and 18-1-712 (3), respectively.

(7) As used in this section:

(h) "Prescriber" means:

(I) A physician or physician assistant licensed pursuant to article 240 of this title 12; ~~or~~

(II) An advanced practice registered nurse, as defined in section 12-255-104 (1), with prescriptive authority pursuant to section 12-255-112; OR

(III) A PHARMACIST.

SECTION 32. In Colorado Revised Statutes, **add with amended and relocated provisions** 10-1-125.3 as follows:

10-1-125.3. Reporting of malpractice claims against pharmacists and pharmacies. (1) **[Formerly 12-280-111 (1)]** Each insurance company licensed to do business in this state and engaged in ~~the~~ writing ~~of~~ malpractice insurance for licensed pharmacists and REGISTERED pharmacies, and each pharmacist or pharmacy that self-insures, shall send to the STATE board OF PHARMACY, in the form prescribed by the ~~board~~ COMMISSIONER IN COLLABORATION WITH THE STATE BOARD OF PHARMACY, information relating to each malpractice claim against a licensed pharmacist OR REGISTERED PHARMACY that is settled or in which judgment is rendered against the insured.

(2) **[Formerly 12-280-111 (2)]** The insurance company or self-insured pharmacist or pharmacy shall provide information relating to each malpractice claim ~~as is deemed~~ THAT THE STATE BOARD OF PHARMACY DEEMS necessary ~~by the board~~ to conduct a further investigation and hearing.

SECTION 33. In Colorado Revised Statutes, **amend** 13-64-303 as follows:

13-64-303. Judgments and settlements - reported - penalties. Any final judgment, settlement, or arbitration award against any health care professional or health care institution for medical malpractice shall be reported within fourteen days by the professional's or institution's medical malpractice insurance carrier in accordance with section 10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 10-1-125, ***10-1-125.3***, or 10-1-125.7, or by the professional or institution if there is no commercial medical malpractice insurance coverage to the licensing agency of the health care professional or health care institution for review, investigation, and, where appropriate, disciplinary or other action. Any health care professional, health care institution, or insurance carrier that knowingly fails to report as required by this section shall be subject to a civil penalty of not more than two thousand five hundred dollars. Such penalty shall be determined and collected by the district court in the city and county of Denver. All penalties collected pursuant to this section shall be transmitted to the state treasurer, who shall credit the same to the general fund.

SECTION 34. In Colorado Revised Statutes, 25-51-104, **amend** (1)(c) and (1)(e) as follows:

25-51-104. Payment and financial resolution. (1) If a patient accepts an offer of compensation made pursuant to section 25-51-103 (5) and receives the compensation, the payment of compensation to the patient is not a payment resulting from:

(c) A malpractice claim settled or in which judgment is rendered against a professional for purposes of reporting by malpractice insurance companies under section 10-1-120, 10-1-120.5, 10-1-121, 10-1-124, 10-1-125, ***10-1-125.3***, 10-1-125.5, or 10-1-125.7;

(e) A judgment, administrative action, settlement, or arbitration award involving malpractice under section 12-200-106 (5), 12-210-105 (5), 12-215-115 (1)(i), 12-220-201 (1)(q) or (1)(r), 12-235-111 (1)(i), 12-240-125 (4)(b)(III), 12-245-226 (7), 12-250-116, 12-255-119 (3)(b)(II), 12-255-120 (1)(dd), 12-275-120 (1)(p) or (1)(v), 12-275-129, ~~12-280-111 (1)~~ ***12-280-126 (1)(t)***, 12-285-120 (1)(o), 12-285-127 (1)(a), 12-285-211 (1)(k), 12-285-216 (1)(a), or 12-290-113 (2)(b)(III).

SECTION 35. In Colorado Revised Statutes, 25.5-2.5-204, **amend** (3)(d) and (4)(a) as follows:

25.5-2.5-204. Eligible prescription drugs - eligible Canadian suppliers - eligible importers - distribution requirements. (3) The following entities are eligible importers and may obtain imported prescription drugs:

(d) A licensed Colorado pharmacist or REGISTERED wholesaler approved by the state department.

(4) (a) The state department shall designate an office or division that must be a ~~licensed pharmaceutical~~ REGISTERED wholesaler or that shall contract with a ~~licensed pharmaceutical~~ wholesaler ~~licensed~~ REGISTERED pursuant to part 3 of article 280 of title 12.

SECTION 36. Effective date. This act takes effect September 1, 2021; except that section 4 of this act takes effect upon passage.

SECTION 37. Safety clause. The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.

Leroy M. Garcia
PRESIDENT OF
THE SENATE

Alec Garnett
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED June 24, 2021 at 11:20 AM
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

Governor Pritzker Signs Bills Expanding Access to HIV and AIDS-Related Care and Prevention

Press Release - Friday, June 10, 2022

Chicago—Governor JB Pritzker signed HB4430 and HB5549 into law today, removing barriers to access for HIV and AIDS care and prevention. HB4430 allows pharmacists to dispense both pre- and post-exposure prophylaxis drugs (PrEP and PEP) without a prior referral from a doctor. HB5549 ensures funding from the African American HIV/AIDS Response Fund will support research centers and resources hubs led by representative members of the community.

"If we want to end the HIV/AIDS epidemic in our state by 2030, then we have to make preventative care like PrEP and PEP accessible to all Illinoisans," **said Governor JB Pritzker.** "These medications are incredibly effective at preventing infection and transmission, and they are essential to our mission of Getting to Zero. My administration knows that these efforts must be equity-centered and proactive to have the biggest impact. That's why we are investing in Black communities that are disproportionately affected by HIV/AIDS. I am proud to sign these bills that bring us one step closer to our ultimate goal: zero new HIV transmissions."

PrEP and PEP reduce the risk of HIV transmission by preventing the HIV virus from replicating in the human body. When taken correctly, PrEP has been shown to reduce risk of contracting HIV by up to 99%. Both drugs require consistent use, with PEP at it's most effective when taken as soon as possible after exposure to the virus. The CDC currently estimates that less than 20% of those eligible for or possibly benefitting from PrEP take the medication.

Inability to access medical care due to financial hardship, cultural stigma, disability, or many other reasons can delay or interrupt the use of these drugs, rendering them less effective or preventing those at risk from adopting use at all. Providing administration and dispersal options from pharmacists makes prophylactic drugs more accessible and can protect countless Illinoisans from HIV/AIDS.

The law also specifies that when these services are provided by a pharmacist, the care must be covered and reimbursed by insurance at the same rate as when provided by a physician. Pharmacists will also receive support and training under the bill to refer patients to other care and support services and for additional testing.

HB5549 provides that the African American HIV/AIDS Response Fund creates and maintains at least one Black-led Center of Excellence HIV Biomedical Resource Hub for every $3,000,000 of available funding. According to the CDC, 46% of people living with HIV/AIDS in Illinois are Black or African American, a disproportionally high rate. However, only 8% of PrEP prescriptions written nationally

each year are for Black or African American individuals. The Fund, originally established in 2006, is designed to target HIV/AIDS transmission reduction services among African Americans.

The Illinois Department of Public Health is a member of Getting to Zero Illinois, an initiative to end the HIV epidemic in Illinois by 2030. Two major tenants of the Getting to Zero plan are addressed by the legislation Governor Pritzker signed today. A central goal of the plan is to increase access and adoption of antivirals like PrEP, which will be far easier with these drugs available through pharmacists. The project also focuses on addressing racial disparities in healthcare to ensure the most at-risk are targeted for prevention and treatment.

"Access to quality healthcare, medicine, and services is a right and not a privilege. We must fight against disparities that disproportionately impact the health of Black and Brown people in this country," **said Lt. Governor Juliana Stratton**. "By signing legislation that sustains the African American HIV/AIDS Response Fund and makes PrEP and PEP more accessible, Illinois is widening the path for equitable care and community based support while fulfilling the promise of creating policy and allocating resources as we move towards our goal of ending the HIV epidemic in Illinois."

"Removing a systemic barrier to these lifesaving medications will put us on a trajectory to end the HIV epidemic as we know it," **State Senator Mike Simmons said.** "People who do not have access to a doctor or may not trust the health care system will have an easier source to access these critical medications, preventing many new HIV infections."

"Historically, Black people living with HIV or AIDS have not received the care and resources they deserve. Amending the historic African American HIV AIDS Response Act to extend it another 25 years and to fund Black-led health hubs are significant steps in the right direction," **said State Rep. Lamont J. Robinson (D-Chicago)**, the lead House sponsor for **House Bill 5549**. "By establishing more Black-led HIV resource hubs, we're guaranteeing Black Illinoisans have the health resources they need, while also working to reduce the disparities in HIV treatment between Black and non-Black residents."

"This law will save lives. Inequitable access, particularly in Black and Brown communities, is a major impediment to our goal of getting to zero new cases of HIV in Illinois," **said State Rep. Kelly M. Cassidy (D-Chicago)**. "Allowing pharmacy access to PEP and PrEP helps address barriers facing these and other marginalized communities, including shame and stigma, and insufficient access to doctors. This law has the potential to help reduce new HIV cases by 90 percent by 2030."

"In 2005, I led the creation of the African American HIV/AIDS Responsive Act in response to the specific impact of the HIV/AIDS epidemic in Illinois disenfranchised communities, and now this law builds upon that act," **said Senate Majority Leader Kimberly A. Lightford (D-Maywood)**. "Creating a Center of Excellence Biomedical Resource Hub for HIV/AIDS preventative care including supportive services is key in treating HIV-infected residents and preventing the continuous spread of this disease, which will help slow down the epidemic."

"Increasing access to PrEP and PEP and retaining more people living with HIV in care are foundational principles of the Getting to Zero Illinois (GTZ-IL) plan," said Timothy S. Jackson, Director of Government Relations for AIDS Foundation Chicago. "However, it's simply not enough to provide treatment to people living with HIV or provide access to PrEP and PEP to the most vulnerable communities. Our response to the epidemic should be rooted in how we address many of the key drivers of HIV in Black, Latinx and LGBTQ+ communities across Illinois including the impact of HIV-related stigma and the dismantling of systemic racism. HB4430 and HB5549 are critical pieces of legislation that inch us one step closer to meeting the state's goal of zero new HIV transmissions by 2030. We thank Governor Pritzker, the Illinois General Assembly, community partners, and advocates for working together to make this moment possible."

"LGBTQ+ people and communities of color in Illinois should be able to access critical health care without experiencing barriers, harassment, and discrimination," **said Michael Ziri, Director of Public Policy at Equality Illinois.** "HB 4430 and HB 5549 are essential measures to help dismantle the structural barriers to care and treatment for LGBTQ+ people and communities of color that are disproportionately impacted by HIV. These initiatives will help Illinois get to zero new HIV infections by 2030. We applaud Governor Pritzker, Leader Lightford, Sen. Simmons, Rep. Cassidy, and Rep. Robinson for their leadership and thank the advocates for their commitment to increasing access to critical health care in Illinois."

"As a healthcare provider for thousands of patients vulnerable to HIV, we at Howard Brown know that there are still too many barriers preventing patients from acessing PrEP," **said David Ernesto Munar, President and CEO of Howard Brown Health**. "The signing of HB4430 is a critical step forward in expanding access to PrEP, especially among the communities that are most disproportionately burdened by HIV. Making HIV preventative services like PrEP more widely available is key in our collective fight to end the HIV epidemic."

"The pandemic has demonstrated the essential need for pharmacists' services in our communities and the quality of care that we provide. HB4430 enables pharmacists to broaden our engagement of care and expand access to PrEP and PEP for our patients. Pharmacists are ready to do our part Getting to Zero in Illinois," **said Garth Reynolds, Executive Director of the Illinois Pharmacists Association.**

"The Illinois African American HIV/AIDS Response Act is the ONLY one of its kind in the entire United States. Despite the disproportionate rates at which AIDS affects the Black community, Illinois is the only state that has an Act to allocate funding specifically for African American led CBOs which provide the optimal cultural competency in programs and services," said Creola A. Kizart-Hampton, President of the Black Leadership Advocacy Coalition for Healthcare Equity in Illinois and President/Founder, GREATERWORKS! INC. "Ensuring funding for full-service HIV/AIDS prevention and health centers across the state is a crucial move toward racial equity of healthcare-- which is the only way the state and nation can 'get to zero.' We are grateful for collective efforts of multiple Black-led CBOs from across the state that have provided dedicated services through the AAHARA including South Side Help Center, Community Wellness Center, Writers Planners & Trainers, and others. We also thank the leadership of Reps. Lamont Robinson and Lashawn Ford, as well as Senators Kimberly Lightford, Mike Simmons, Jacqueline Collins and others for championing this legislation. "

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Illinois Clinical Laboratory and Blood Bank Act is amended by changing Sections 7-101 and 7-102 as follows:

(210 ILCS 25/7-101) (from Ch. 111 1/2, par. 627-101)

Sec. 7-101. Examination of specimens. A clinical laboratory shall examine specimens only at the request of (i) a licensed physician, (ii) a licensed dentist, (iii) a licensed podiatric physician, (iv) a licensed optometrist, (v) a licensed physician assistant, (v-A) a licensed advanced practice registered nurse, (vi) an authorized law enforcement agency or, in the case of blood alcohol, at the request of the individual for whom the test is to be performed in compliance with Sections 11-501 and 11-501.1 of the Illinois Vehicle Code, ~~or~~ (vii) a genetic counselor with the specific authority from a referral to order a test or tests pursuant to subsection (b) of Section 20 of the Genetic Counselor Licensing Act<u>, or (viii) a pharmacist in accordance with Section 43.5 of the Pharmacy Practice Act</u>. If the request to a laboratory is oral, the physician or other authorized person shall submit a written request to the laboratory within 48 hours. If the

laboratory does not receive the written request within that period, it shall note that fact in its records. For purposes of this Section, a request made by electronic mail or fax constitutes a written request.

(Source: P.A. 99-173, eff. 7-29-15; 100-513, eff. 1-1-18.)

(210 ILCS 25/7-102) (from Ch. 111 1/2, par. 627-102)

Sec. 7-102. Reports of test results.

(a) Clinical laboratory test results may be reported or transmitted to:

(1) the licensed physician or other authorized person who requested the test, their designee, or both;

(2) any health care provider who is providing treatment to the patient;

(3) an electronic health information exchange for the purposes of transmitting, using, or disclosing clinical laboratory test results in any manner required or permitted by HIPAA; and~~.~~

(4) a pharmacist in accordance with Section 43.5 of the Pharmacy Practice Act.

(b) No interpretation, diagnosis, or prognosis or suggested treatment shall appear on the laboratory report form, except that a report made by a physician licensed to practice medicine in Illinois, a dentist licensed in Illinois, or an optometrist licensed in Illinois may include such information.

(c) Nothing in this Act prohibits the sharing of information as authorized in Section 2.1 of the Department of Public Health Act.

(Source: P.A. 98-185, eff. 1-1-14; 98-1046, eff. 1-1-15.)

Section 10. The Illinois Insurance Code is amended by adding Section 356z.45 as follows:

(215 ILCS 5/356z.45)

Sec. 356z.45 ~~356z.43~~. Coverage for patient care services provided by a pharmacist. A group or individual policy of accident and health insurance or a managed care plan that is amended, delivered, issued, or renewed on or after January 1, 2023 shall provide coverage for health care or patient care services provided by a pharmacist if:

(1) the pharmacist meets the requirements and scope of practice as set forth in Section 43 or Section 43.5 of the Pharmacy Practice Act;

(2) the health plan provides coverage for the same service provided by a licensed physician, an advanced practice registered nurse, or a physician assistant;

(3) the pharmacist is included in the health benefit plan's network of participating providers; and

(4) a reimbursement has been successfully negotiated in good faith between the pharmacist and the health plan.

(Source: P.A. 102-103, eff. 1-1-23; revised 10-26-21.)

Section 15. The Pharmacy Practice Act is amended by changing Sections 3 and 9 and by adding Section 43.5 as follows:

(225 ILCS 85/3)

(Section scheduled to be repealed on January 1, 2023)

Sec. 3. Definitions. For the purpose of this Act, except where otherwise limited therein:

(a) "Pharmacy" or "drugstore" means and includes every store, shop, pharmacy department, or other place where pharmacist care is provided by a pharmacist (1) where drugs, medicines, or poisons are dispensed, sold or offered for sale at retail, or displayed for sale at retail; or (2) where prescriptions of physicians, dentists, advanced practice registered nurses, physician assistants, veterinarians, podiatric physicians, or optometrists, within the limits of their licenses, are compounded, filled, or dispensed; or (3) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacist", "Druggist", "Pharmacy", "Pharmaceutical Care", "Apothecary", "Drugstore", "Medicine Store", "Prescriptions", "Drugs", "Dispensary", "Medicines", or any word or words of similar or like import, either in the English language or any other language; or (4) where the characteristic prescription sign (Rx) or similar design is exhibited; or (5) any store, or

shop, or other place with respect to which any of the above words, objects, signs or designs are used in any advertisement.

(b) "Drugs" means and includes (1) articles recognized in the official United States Pharmacopoeia/National Formulary (USP/NF), or any supplement thereto and being intended for and having for their main use the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as approved by the United States Food and Drug Administration, but does not include devices or their components, parts, or accessories; and (2) all other articles intended for and having for their main use the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as approved by the United States Food and Drug Administration, but does not include devices or their components, parts, or accessories; and (3) articles (other than food) having for their main use and intended to affect the structure or any function of the body of man or other animals; and (4) articles having for their main use and intended for use as a component or any articles specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.

(c) "Medicines" means and includes all drugs intended for human or veterinary use approved by the United States Food and Drug Administration.

(d) "Practice of pharmacy" means:

(1) the interpretation and the provision of assistance

in the monitoring, evaluation, and implementation of prescription drug orders;

(2) the dispensing of prescription drug orders;

(3) participation in drug and device selection;

(4) drug administration limited to the administration of oral, topical, injectable, and inhalation as follows:

(A) in the context of patient education on the proper use or delivery of medications;

(B) vaccination of patients 7 years of age and older pursuant to a valid prescription or standing order, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures. Eligible vaccines are those listed on the U.S. Centers for Disease Control and Prevention (CDC) Recommended Immunization Schedule, the CDC's Health Information for International Travel, or the U.S. Food and Drug Administration's Vaccines Licensed and Authorized for Use in the United States. As applicable to the State's Medicaid program and other payers, vaccines ordered and administered in accordance with this subsection shall be covered and reimbursed at no

less than the rate that the vaccine is reimbursed when ordered and administered by a physician;

(B-5) following the initial administration of long-acting or extended-release form opioid antagonists by a physician licensed to practice medicine in all its branches, administration of injections of long-acting or extended-release form opioid antagonists for the treatment of substance use disorder, pursuant to a valid prescription by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions, including, but not limited to, respiratory depression and the performance of cardiopulmonary resuscitation, set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures;

(C) administration of injections of alpha-hydroxyprogesterone caproate, pursuant to a valid prescription, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital

pharmacy and therapeutics committee policies and procedures; and

(D) administration of injections of long-term antipsychotic medications pursuant to a valid prescription by a physician licensed to practice medicine in all its branches, upon completion of appropriate training conducted by an Accreditation Council of Pharmaceutical Education accredited provider, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures.

(5) (blank);

(6) drug regimen review;

(7) drug or drug-related research;

(8) the provision of patient counseling;

(9) the practice of telepharmacy;

(10) the provision of those acts or services necessary to provide pharmacist care;

(11) medication therapy management;

(12) the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper

and safe storage of drugs and devices, and maintenance of required records; ~~and~~

(13) the assessment and consultation of patients and dispensing of hormonal contraceptives; and~~.~~

(14) the initiation, dispensing, or administration of drugs, laboratory tests, assessments, referrals, and consultations for human immunodeficiency virus pre-exposure prophylaxis and human immunodeficiency virus post-exposure prophylaxis under Section 43.5.

A pharmacist who performs any of the acts defined as the practice of pharmacy in this State must be actively licensed as a pharmacist under this Act.

(e) "Prescription" means and includes any written, oral, facsimile, or electronically transmitted order for drugs or medical devices, issued by a physician licensed to practice medicine in all its branches, dentist, veterinarian, podiatric physician, or optometrist, within the limits of his or her license, by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice registered nurse in accordance with subsection (g) of Section 4, containing the following: (1) name of the patient; (2) date when prescription was issued; (3) name and strength of drug or description of the medical device prescribed; and (4) quantity; (5) directions for use; (6) prescriber's name, address, and signature; and (7) DEA registration number where required, for controlled substances. The prescription may, but

is not required to, list the illness, disease, or condition for which the drug or device is being prescribed. DEA registration numbers shall not be required on inpatient drug orders. A prescription for medication other than controlled substances shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise.

(f) "Person" means and includes a natural person, partnership, association, corporation, government entity, or any other legal entity.

(g) "Department" means the Department of Financial and Professional Regulation.

(h) "Board of Pharmacy" or "Board" means the State Board of Pharmacy of the Department of Financial and Professional Regulation.

(i) "Secretary" means the Secretary of Financial and Professional Regulation.

(j) "Drug product selection" means the interchange for a prescribed pharmaceutical product in accordance with Section 25 of this Act and Section 3.14 of the Illinois Food, Drug and Cosmetic Act.

(k) "Inpatient drug order" means an order issued by an authorized prescriber for a resident or patient of a facility licensed under the Nursing Home Care Act, the ID/DD Community Care Act, the MC/DD Act, the Specialized Mental Health Rehabilitation Act of 2013, the Hospital Licensing Act, or the

University of Illinois Hospital Act, or a facility which is operated by the Department of Human Services (as successor to the Department of Mental Health and Developmental Disabilities) or the Department of Corrections.

(k-5) "Pharmacist" means an individual health care professional and provider currently licensed by this State to engage in the practice of pharmacy.

(l) "Pharmacist in charge" means the licensed pharmacist whose name appears on a pharmacy license and who is responsible for all aspects of the operation related to the practice of pharmacy.

(m) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient in accordance with applicable State and federal laws and regulations. "Dispense" or "dispensing" does not mean the physical delivery to a patient or a patient's representative in a home or institution by a designee of a pharmacist or by common carrier. "Dispense" or "dispensing" also does not mean the physical delivery of a drug or medical device to a patient or patient's representative by a pharmacist's designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open.

(n) "Nonresident pharmacy" means a pharmacy that is

located in a state, commonwealth, or territory of the United States, other than Illinois, that delivers, dispenses, or distributes, through the United States Postal Service, commercially acceptable parcel delivery service, or other common carrier, to Illinois residents, any substance which requires a prescription.

(o) "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing patterns. Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs and (ii) the prescribing practitioner has requested that the drug be compounded.

(p) (Blank).

(q) (Blank).

(r) "Patient counseling" means the communication between a pharmacist or a student pharmacist under the supervision of a

pharmacist and a patient or the patient's representative about the patient's medication or device for the purpose of optimizing proper use of prescription medications or devices. "Patient counseling" may include without limitation (1) obtaining a medication history; (2) acquiring a patient's allergies and health conditions; (3) facilitation of the patient's understanding of the intended use of the medication; (4) proper directions for use; (5) significant potential adverse events; (6) potential food-drug interactions; and (7) the need to be compliant with the medication therapy. A pharmacy technician may only participate in the following aspects of patient counseling under the supervision of a pharmacist: (1) obtaining medication history; (2) providing the offer for counseling by a pharmacist or student pharmacist; and (3) acquiring a patient's allergies and health conditions.

(s) "Patient profiles" or "patient drug therapy record" means the obtaining, recording, and maintenance of patient prescription information, including prescriptions for controlled substances, and personal information.

(t) (Blank).

(u) "Medical device" or "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, required under federal law to bear the label "Caution: Federal law requires dispensing by or

on the order of a physician". A seller of goods and services who, only for the purpose of retail sales, compounds, sells, rents, or leases medical devices shall not, by reasons thereof, be required to be a licensed pharmacy.

(v) "Unique identifier" means an electronic signature, handwritten signature or initials, thumb print, or other acceptable biometric or electronic identification process as approved by the Department.

(w) "Current usual and customary retail price" means the price that a pharmacy charges to a non-third-party payor.

(x) "Automated pharmacy system" means a mechanical system located within the confines of the pharmacy or remote location that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(y) "Drug regimen review" means and includes the evaluation of prescription drug orders and patient records for (1) known allergies; (2) drug or potential therapy contraindications; (3) reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications; (4) reasonable directions for use; (5) potential or actual adverse drug reactions; (6) drug-drug interactions; (7) drug-food interactions; (8) drug-disease contraindications; (9) therapeutic duplication; (10) patient laboratory values when

authorized and available; (11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and (12) abuse and misuse.

(z) "Electronically transmitted prescription" means a prescription that is created, recorded, or stored by electronic means; issued and validated with an electronic signature; and transmitted by electronic means directly from the prescriber to a pharmacy. An electronic prescription is not an image of a physical prescription that is transferred by electronic means from computer to computer, facsimile to facsimile, or facsimile to computer.

(aa) "Medication therapy management services" means a distinct service or group of services offered by licensed pharmacists, physicians licensed to practice medicine in all its branches, advanced practice registered nurses authorized in a written agreement with a physician licensed to practice medicine in all its branches, or physician assistants authorized in guidelines by a supervising physician that optimize therapeutic outcomes for individual patients through improved medication use. In a retail or other non-hospital pharmacy, medication therapy management services shall consist of the evaluation of prescription drug orders and patient medication records to resolve conflicts with the following:

(1) known allergies;

(2) drug or potential therapy contraindications;

(3) reasonable dose, duration of use, and route of

administration, taking into consideration factors such as age, gender, and contraindications;

(4) reasonable directions for use;

(5) potential or actual adverse drug reactions;

(6) drug-drug interactions;

(7) drug-food interactions;

(8) drug-disease contraindications;

(9) identification of therapeutic duplication;

(10) patient laboratory values when authorized and available;

(11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and

(12) drug abuse and misuse.

"Medication therapy management services" includes the following:

(1) documenting the services delivered and communicating the information provided to patients' prescribers within an appropriate time frame, not to exceed 48 hours;

(2) providing patient counseling designed to enhance a patient's understanding and the appropriate use of his or her medications; and

(3) providing information, support services, and resources designed to enhance a patient's adherence with his or her prescribed therapeutic regimens.

"Medication therapy management services" may also include

patient care functions authorized by a physician licensed to practice medicine in all its branches for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician.

"Medication therapy management services" in a licensed hospital may also include the following:

(1) reviewing assessments of the patient's health status; and

(2) following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders.

(bb) "Pharmacist care" means the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes that improve patient health, quality of life, and comfort and enhance patient safety.

(cc) "Protected health information" means individually identifiable health information that, except as otherwise provided, is:

(1) transmitted by electronic media;

(2) maintained in any medium set forth in the definition of "electronic media" in the federal Health Insurance Portability and Accountability Act; or

(3) transmitted or maintained in any other form or medium.

"Protected health information" does not include individually identifiable health information found in:

(1) education records covered by the federal Family Educational Right and Privacy Act; or

(2) employment records held by a licensee in its role as an employer.

(dd) "Standing order" means a specific order for a patient or group of patients issued by a physician licensed to practice medicine in all its branches in Illinois.

(ee) "Address of record" means the designated address recorded by the Department in the applicant's application file or licensee's license file maintained by the Department's licensure maintenance unit.

(ff) "Home pharmacy" means the location of a pharmacy's primary operations.

(gg) "Email address of record" means the designated email address recorded by the Department in the applicant's application file or the licensee's license file, as maintained by the Department's licensure maintenance unit.

(Source: P.A. 101-349, eff. 1-1-20; 102-16, eff. 6-17-21; 102-103, eff. 1-1-22; 102-558, eff. 8-20-21; revised 10-26-21.)

(225 ILCS 85/9) (from Ch. 111, par. 4129)

(Section scheduled to be repealed on January 1, 2023)

Sec. 9. Licensure as registered pharmacy technician.

(a) Any person shall be entitled to licensure as a registered pharmacy technician who is of the age of 16 or over, has not engaged in conduct or behavior determined to be grounds for discipline under this Act, is attending or has graduated from an accredited high school or comparable school or educational institution or received a high school equivalency certificate, and has filed a written or electronic application for licensure on a form to be prescribed and furnished by the Department for that purpose. The Department shall issue a license as a registered pharmacy technician to any applicant who has qualified as aforesaid, and such license shall be the sole authority required to assist licensed pharmacists in the practice of pharmacy, under the supervision of a licensed pharmacist. A registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, ~~or~~ clinical conflict resolution, or providing patients prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis.

(b) Beginning on January 1, 2017, within 2 years after initial licensure as a registered pharmacy technician, the licensee must meet the requirements described in Section 9.5 of this Act and become licensed as a registered certified pharmacy technician. If the licensee has not yet attained the age of 18, then upon the next renewal as a registered pharmacy

technician, the licensee must meet the requirements described in Section 9.5 of this Act and become licensed as a registered certified pharmacy technician. This requirement does not apply to pharmacy technicians registered prior to January 1, 2008.

(c) Any person registered as a pharmacy technician who is also enrolled in a first professional degree program in pharmacy in a school or college of pharmacy or a department of pharmacy of a university approved by the Department or has graduated from such a program within the last 18 months, shall be considered a "student pharmacist" and entitled to use the title "student pharmacist". A student pharmacist must meet all of the requirements for licensure as a registered pharmacy technician set forth in this Section excluding the requirement of certification prior to the second license renewal and pay the required registered pharmacy technician license fees. A student pharmacist may, under the supervision of a pharmacist, assist in the practice of pharmacy and perform any and all functions delegated to him or her by the pharmacist.

(d) Any person seeking licensure as a pharmacist who has graduated from a pharmacy program outside the United States must register as a pharmacy technician and shall be considered a "student pharmacist" and be entitled to use the title "student pharmacist" while completing the 1,200 clinical hours of training approved by the Board of Pharmacy described and for no more than 18 months after completion of these hours. These individuals are not required to become registered

certified pharmacy technicians while completing their Board approved clinical training, but must become licensed as a pharmacist or become licensed as a registered certified pharmacy technician before the second pharmacy technician license renewal following completion of the Board approved clinical training.

(e) The Department shall not renew the registered pharmacy technician license of any person who has been licensed as a registered pharmacy technician with the designation "student pharmacist" who: (1) has dropped out of or been expelled from an ACPE accredited college of pharmacy; (2) has failed to complete his or her 1,200 hours of Board approved clinical training within 24 months; or (3) has failed the pharmacist licensure examination 3 times. The Department shall require these individuals to meet the requirements of and become licensed as a registered certified pharmacy technician.

(f) The Department may take any action set forth in Section 30 of this Act with regard to a license pursuant to this Section.

(g) Any person who is enrolled in a non-traditional Pharm.D. program at an ACPE accredited college of pharmacy and is licensed as a registered pharmacist under the laws of another United States jurisdiction shall be permitted to engage in the program of practice experience required in the academic program by virtue of such license. Such person shall be exempt from the requirement of licensure as a registered

pharmacy technician or registered certified pharmacy technician while engaged in the program of practice experience required in the academic program.

An applicant for licensure as a registered pharmacy technician may assist a pharmacist in the practice of pharmacy for a period of up to 60 days prior to the issuance of a license if the applicant has submitted the required fee and an application for licensure to the Department. The applicant shall keep a copy of the submitted application on the premises where the applicant is assisting in the practice of pharmacy. The Department shall forward confirmation of receipt of the application with start and expiration dates of practice pending licensure.

(Source: P.A. 100-497, eff. 9-8-17; 101-621, eff. 1-1-20.)

(225 ILCS 85/43.5 new)

Sec. 43.5. HIV prophylaxis. In accordance with a standing order by a physician licensed to practice medicine in all its branches or the medical director of a county or local health department, a pharmacist may provide patients with prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis.

A pharmacist may provide initial assessment and dispensing of prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis. If a patient's HIV test results are reactive, the pharmacist shall

refer the patient to an appropriate health care professional or clinic. If the patient's HIV test results are nonreactive, the pharmacist may initiate human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis to eligible patients.

The standing order must be consistent with the current version of the guidelines of the Centers for Disease Control and Prevention, guidelines of the United States Preventive Services Task Force, or generally recognized evidence-based clinical guidelines.

A pharmacist must communicate the services provided under this Section to the patient and the patient's primary health care provider or other health care professional or clinic, if known. If there is no primary health care provider provided by the patient, then the pharmacist shall give the patient a list of primary health care providers, other health care professionals, and clinics in the area.

The services provided under this Section shall be appropriately documented and retained in a confidential manner consistent with State HIV confidentiality requirements.

The services provided under this Section shall take place in a private manner.

A pharmacist shall complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the initiation, dispensing, or administration of drugs,

laboratory tests, assessments, referrals, and consultations for human immunodeficiency virus pre-exposure prophylaxis and human immunodeficiency virus post-exposure prophylaxis.

Section 20. The Illinois Public Aid Code is amended by changing Section 5-5.12d as follows:

(305 ILCS 5/5-5.12d)

Sec. 5-5.12d. Coverage for patient care services for hormonal contraceptives, human immunodeficiency virus pre-exposure prophylaxis, and human immunodeficiency virus post-exposure prophylaxis provided by a pharmacist.

(a) Subject to approval by the federal Centers for Medicare and Medicaid Services, the medical assistance program, including both the fee-for-service and managed care medical assistance programs established under this Article, shall cover patient care services provided by a pharmacist for hormonal contraceptives, human immunodeficiency virus pre-exposure prophylaxis, and human immunodeficiency virus post-exposure prophylaxis assessment and consultation.

(b) The Department shall establish a fee schedule for patient care services provided by a pharmacist under Sections 43 and 43.5 of the Pharmacy Practice Act and shall be covered and reimbursed at no less than 85% of the rate that the services are reimbursed when provided by a physician ~~for hormonal contraceptives assessment and consultation~~.

(c) The rate of reimbursement for patient care services provided by a pharmacist for hormonal contraceptives, human immunodeficiency virus pre-exposure prophylaxis, and human immunodeficiency virus post-exposure prophylaxis assessment and consultation shall be at 85% of the fee schedule for physician services by the medical assistance program.

(d) A pharmacist must be enrolled in the medical assistance program as an ordering and referring provider prior to providing patient care services for hormonal contraceptives, human immunodeficiency virus pre-exposure prophylaxis, and human immunodeficiency virus post-exposure prophylaxis assessment and consultation that is submitted by a pharmacy or pharmacist provider for reimbursement pursuant to this Section.

(e) The Department shall apply for any necessary federal waivers or approvals to implement this Section by January 1, 2023 ~~2022~~.

(f) This Section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, pharmacist services provided under this Code or authorized under the Illinois Title XIX State Plan.

(g) The Department shall submit to the Joint Committee on Administrative Rules administrative rules for this Section as soon as practicable but no later than 6 months after federal approval is received.

(Source: P.A. 102-103, eff. 1-1-22.)

Section 99. Effective date. This Act takes effect January 1, 2023.

§13786-E. Prescribing, dispensing and administering HIV prevention drugs

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "CDC guidelines" means guidelines related to nonoccupational exposure to potential HIV infection, or any subsequent guidelines, published by the federal Department of Health and Human Services, Centers for Disease Control and Prevention. [PL 2021, c. 265, §6 (NEW).]

B. "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure prophylaxis drug or other drug approved for the prevention of HIV infection by the federal Food and Drug Administration. [PL 2021, c. 265, §6 (NEW).]

C. "Post-exposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines following potential exposure to HIV infection. [PL 2021, c. 265, §6 (NEW).]

D. "Preexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines to prevent HIV infection. [PL 2021, c. 265, §6 (NEW).]

[PL 2021, c. 265, §6 (NEW).]

2. Authorization. Notwithstanding any provision of law to the contrary and as authorized by the board in accordance with rules adopted under subsection 3, a pharmacist may prescribe, dispense and administer HIV prevention drugs pursuant to a standing order or collaborative practice agreement or to protocols developed by the board for when there is no prescription drug order, standing order or collaborative practice agreement in accordance with the requirements in this subsection and may also order laboratory testing for HIV infection as necessary.

A. Before furnishing an HIV prevention drug to a patient, a pharmacist shall complete a training program approved by the board on the use of protocols developed by the board for prescribing, dispensing and administering an HIV prevention drug, on the requirements for any laboratory testing for HIV infection and on guidelines for prescription adherence and best practices to counsel patients prescribed an HIV prevention drug. [PL 2021, c. 265, §6 (NEW).]

B. A pharmacist shall dispense or administer a preexposure prophylaxis drug in at least a 30-day supply, and up to a 60-day supply, as long as all of the following conditions are met:

(1) The patient tests negative for HIV infection, as documented by a negative HIV test result obtained within the previous 7 days. If the patient does not provide evidence of a negative HIV test result in accordance with this subparagraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of primary care providers and clinics within a reasonable travel distance of the patient's residence;

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reporting checklist of acute HIV infection signs and symptoms;

(3) The patient does not report taking any contraindicated medications;

(4) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the ongoing use of a preexposure prophylaxis drug. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for a preexposure prophylaxis drug and that a pharmacist may not dispense or administer more than a 60-day supply of a preexposure prophylaxis drug to a single patient once every 2 years without a prescription;

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the patient profile record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis drugs dispensed or administered to each patient;

(6) The pharmacist does not dispense or administer more than a 60-day supply of a preexposure prophylaxis drug to a single patient once every 2 years, unless otherwise directed by a practitioner; and

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this paragraph. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care. [PL 2021, c. 265, §6 (NEW).]

C. A pharmacist shall dispense or administer a complete course of a post-exposure prophylaxis drug as long as all of the following conditions are met:

(1) The pharmacist screens the patient and determines that the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for a post-exposure prophylaxis drug under CDC guidelines;

(2) The pharmacist provides HIV testing to the patient or determines that the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for a post-exposure prophylaxis drug under this subsection, the pharmacist may dispense or administer a post-exposure prophylaxis drug;

(3) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the use of a post-exposure prophylaxis drug. The pharmacist shall also inform the patient of the availability of a preexposure prophylaxis drug for persons who are at substantial risk of acquiring HIV; and

(4) The pharmacist notifies the patient's primary care provider of the dispensing or administering of the post-exposure prophylaxis drug. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care. [PL 2021, c. 265, §6 (NEW).]

[PL 2021, c. 265, §6 (NEW).]

3. Rules; protocols. The board by rule shall establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs in accordance with subsection 2, including adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement. Rules adopted under this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[PL 2021, c. 265, §6 (NEW).]

SECTION HISTORY

PL 2021, c. 265, §6 (NEW).

NEVADA STATE BOARD OF PHARMACY

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Notice to Pharmacists and Technicians
04/22/2022

Pharmacist Authorized to Prescribe, Dispense, and Administer Drugs to Prevent the Acquisition of Human Immunodeficiency Virus (HIV) and to Perform Certain Tests

The need for access to certain drugs to prevent the acquisition of human immunodeficiency virus (HIV) preexposure (PREP) and postexposure (PEP) was recognized, introduced, and passed as Senate Bill 325 (SB 325) during the 2021 Legislative Session. The language to the bill can be located here: https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bill/7959/Text. To accomplish this end, SB 325 required the Nevada State Board of Pharmacy to establish a protocol to permit a pharmacist to prescribe, dispense, and administer drugs to prevent the acquisition of HIV, and to perform certain laboratory tests. In summary, the regulation will require a pharmacist who wishes to prescribe, dispense and administer PREP and PEP drugs to:

1. Complete a course of training concerning the prescribing, dispensing and administering of drugs approved by the United States Food and Drug Administration for preventing the acquisition of HIV;
2. Maintain and keep readily available proof of completion of such course of training while the pharmacist prescribes, dispenses or administers such drugs and for at least two (2) years following that prescribing, dispensing and administering; and
3. Maintain professional liability insurance coverage of at least $1,000,000.

Once a pharmacist has completed the aforementioned, the pharmacist must:

1. Complete an assessment of the patient, which includes
    a. HIV test;
    b. Renal function test;
    c. Hepatitis B test; and
    d. An evaluation for any signs and symptoms of acute HIV infection*;*
2. Counsel the patient and provide information about the drug dispensed or administered; and
3. Comply with the publications adopted by reference by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, “Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update – A Clinical Practice Guideline” and “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV”.

A pharmacist may prescribe, dispense, or administer up to a 30-day supply of a drug approved by the United States Food and Drug Administration for preventing the acquisition of HIV **to continue the patient's treatment** without completing the requirements of laboratory testing if the pharmacist:

1. Makes a good faith effort to obtain and review the laboratory history of the patient;
2. Completes an assessment of the patient;
3. Reviews potential side effects with the patient; and
4. Determines that continuing the treatment outweighs the risk of discontinuing treatment.

A pharmacist may prescribe, dispense, or administer **PEP** drug approved by the United States Food and Drug Administration for preventing the acquisition of HIV **immediately upon the request of a patient who has recently been exposed to HIV**. Before continuation of treatment using such drugs beyond the initial prescribing, dispensing, or administering, complete an assessment of the patient which includes, without limitation:

1. A test for HIV;
2. A pregnancy test if the patient is a woman of child-bearing age;
3. a test for liver function;
4. A test for renal function;
5. A test and screening for sexually transmitted infections;
6. A test for hepatitis B; and
7. A test for hepatitis C.

Pharmacists are required to comply with the provisions of chapter 441A of NRS and chapter 441A of NAC concerning the reporting of cases of communicable diseases. The regulation implementing SB325 can be found here: https://www.leg.state.nv.us/Register/2021Register/R039-21AP.pdf.

PROTOCOL FOR PHARMACIST PRESCRIBING OF DANGEROUS DRUGS IN CONJUNCTION WITH POINT-OF-CARE TESTING (POCT)

I. TITLE: New Mexico Pharmacist prescribing of dangerous drugs in conjunction with point-of-care testing (POCT) is intended to support and pursuant to, New Mexico Board of Pharmacy ("Board") Regulation (16.19.26 NMAC).

II. PURPOSE: To assist pharmacists in providing safe and effective prescribing of dangerous drugs in conjunction with CLIA-Waived point-of-care testing (POCT) in New Mexico. Additionally, to set criteria for properly trained and certified pharmacists to prescribe in a safe manner for all eligible and appropriately screened patients in New Mexico who would benefit from testing and therapy.[1-5]

a. HIV Post-Exposure Prophylaxis (PEP) therapy for patients who have potentially been exposed to HIV within the past 72 hours, in a manner that puts them at risk for HIV infection;
b. COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy; (COVID Prophylaxis Therapy Removed)
c. Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis antimicrobial therapy;
d. Influenza antiviral therapy.

III. BACKGROUND: Studies have shown that pharmacist prescribing of dangerous drugs in conjunction with POCT can be beneficial, safe, and effective - see **References, Section XVIII**.[12-32]

IV. **GUIDELINES**: All pharmacists participating in prescriptive authority for dangerous drugs in conjunction with POCT will:

a. Follow the current prevailing evidence-based guidelines and recognized standards of practice,
b. Follow the current Board-approved pharmacist prescriptive authority training and protocol, including appropriate screening, history, assessment, patient education, and referrals.
c. Follow the applicable **Pharmacist Procedures Section XII and Formulary Section XIII**, as detailed in the Board approved protocol.
d. Assess the need for referral to the patient's primary care provider, urgent care, emergency care, local clinic, or specialty clinic for other recommended testing and follow-up, including patients not eligible for POCT, as appropriate.

V. PHARMACIST MANDATES: All pharmacists participating in prescriptive authority for dangerous drugs in conjunction with POCT must:

a. Follow the current Board approved protocol and have on-site access to the protocol.
b. Possess the knowledge, skills and abilities to appropriately engage in dangerous drug prescribing in conjunction with POCT, and complete the Board approved required training course.
c. Maintain required documentation, including patient records, prescriptions and POCT results.

d. Keep patient specific documents securely stored, electronically or in a locked cabinet in the pharmacy, and HIPAA policies must be followed, as with other pharmacy related materials. These documents will include informed consent, screening documents, and other relevant information, as appropriate.
e. Follow-up with patients, according to prevailing evidence-based guidelines, and clinical studies, as appropriate.
f. Satisfactorily complete the Board approved pharmacist prescriptive authority training course(s).
g. Provide proper notification to the patient's primary care provider of the prescription and POCT results, with patient approval, as stated in the informed consent.
h. Provide proper notification to the New Mexico Department of Health (NMDOH), as required.
i. Follow CLIA-waived requirements for utilized FDA or Emergency Use Authorization (EUA) tests.
j. Complete 2 hours of live ACPE accredited continuing education credits in POCT per category of testing and treatment, every 2 years, to maintain active certification.
k. Documentation of POCT results must:
    i. Be maintained by the certified prescribing pharmacist, and POCT results must be provided to the patient.
    ii. Be sent to the NMDOH as required by New Mexico law.
    iii. Be provided to others (i.e. primary care providers, employers, etc.), upon patient request.

VI. HEALTH ASSESSMENT: Proper assessment of the patient presenting for POCT may include the following:

a. Patient history
b. Family history
c. Social history
d. Current living environment
e. Concurrent illness
f. Allergies and hypersensitivities
g. Medication history
h. Risk factors
i. Additional exposures
j. Physical assessment
k. Other information, as appropriate

VII. CONTRAINDICATIONS AND PRECAUTIONS:

a. Pharmacists with prescriptive authority will follow current prevailing evidence-based guidelines, recognized standards of practice, and professional prescribing information.

VIII. PATIENT EDUCATION: Patient materials can include:

a. General medical condition(s)
b. Drug information
c. Adherence
d. Side effects

e. Referral/follow-up information
f. Other education, as appropriate

IX. REFERRALS:

The pharmacist will provide timely and appropriate referrals as indicated. Referrals may include the patient's primary care provider, urgent care, emergency care, local provider, local specialty clinic, or NMDOH for complete evaluation. The pharmacist will refer under the following circumstances:

i. a patient with a known allergy that interacts or may interact with the dangerous drug(s) in conjunction with POCT, and wishing intervention;
ii. a patient experiencing intolerable side effects or sign/symptoms, and wishing intervention;
iii. if the certified prescribing pharmacist is unable to prescribe indicated dangerous drug(s) in conjunction with POCT for a patient. The pharmacist will communicate timely with the patient regarding the pharmacist's inability and referral.
iv. all patients exhibiting any of the exclusion criteria.

X. INFORMED CONSENT: The informed consent form and process will be provided during the pharmacist training course(s). Informed consent must be obtained from the patient prior to POCT and prescribing of dangerous drugs.

XI. RECORDS:

a. Consent form
b. Patient documentation, including medical history
c. Records of notification and reporting
d. Records of patient education provided
e. Billing
f. Prescription(s)
g. Additional records

XII. PHARMACIST PRESCRIBING OF DANGEROUS DRUGS IN CONJUNCTION WITH POINT-OF-CARE TESTING (POCT) PROCEDURES:

a. **HIV PEP Therapy:**
    i. This service shall be available to all appropriately screened patients in New Mexico, who have potentially been exposed to HIV, within the past 72 hours, in a manner that puts them at risk of HIV infection. Eligibility will be consistent with the recommended and prevailing evidence-based guidelines.[1,2] Screening information will include:
        1. HIV status of source, if known
        2. Type of exposure
        3. Timing of exposure
        4. Reported history of renal dysfunction
        5. Other information, as appropriate
    ii. The patient's current HIV status will be evaluated by the certified prescribing pharmacist performing POCT, using the rapid HIV Ab/Ag test, as deemed appropriate by the device manufacturer.

1. If the result of the HIV testing is positive, the patient will **NOT** be prescribed HIV PEP therapy and will be immediately referred to their primary care provider, local HIV clinic, or NMDOH for complete evaluation, along with completion of NMDOH reporting requirements.
2. If the patient refuses POCT, HIV PEP therapy should not be withheld, if the patient is otherwise eligible, and refusal should be documented.

iii. All patients who are eligible for HIV PEP therapy, will receive a prescription written for a 1-month supply, consistent with the recommended and prevailing evidence-based guidelines or NMDOH HIV PEP therapy recommendations, with no additional refills.[1,2,6]

iv. All patients who are eligible to receive HIV PEP therapy, will receive patient education and counseling on drug information, adherence, side effects, and other education materials, as appropriate.

v. All patients prescribed HIV PEP therapy, must also be referred to their primary care provider, local HIV clinic, or NMDOH, for other recommended laboratory tests and follow-up within 7 days.

vi. All patients who are eligible for HIV PEP therapy, but have reported history of renal dysfunction, are ≤12 years of age, or have other contraindications to the therapy, will not be prescribed therapy by the certified pharmacist and must be referred to their primary care provider, local HIV clinic, or NMDOH, for complete evaluation.

vii. All referrals in which HIV PEP therapy is potentially indicated, but unable to be prescribed by the certified prescribing pharmacist, should include timely and immediate pharmacist communication with the patient's primary care provider, local HIV clinic, or NMDOH, to ensure initiation of HIV PEP therapy within 72 hours of having potentially been exposed to HIV.

b. **COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 Therapy:** COVID Prophylaxis Removed

i. This service shall be available to all eligible, appropriately screened patients in New Mexico. Proper personal protective equipment (PPE) will be worn when performing the COVID-19 POCT, for the protection of the patient and the certified prescribing pharmacist.[7] A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.
   1. The patient's current signs/symptoms, age (patients must be >3 years of age), weight, temperature, medical history, current medications, and known drug allergies, will be evaluated by the certified prescribing pharmacist.

ii. All patients who wish to start COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy, must meet the eligibility criteria, based on and consistent with the

recommended and prevailing evidence-based guidelines or clinical studies.[3]

iii. The prescription will be written for an appropriate supply of COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy, consistent with the recommended and prevailing evidence-based guidelines or clinical studies, with no additional refills, as authorized by the certified prescribing pharmacist and in the approved **Formulary, Section XIII**.[3]

iv. All patients who are eligible to COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

v. All patients who are eligible for COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local clinic, or the NMDOH, for further evaluation.

vi. All patients, who are experiencing emergency signs/symptoms of possible COVID-19, will be given a referral to the local hospital for further evaluation.

c. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

i. This service shall be available to all eligible, appropriately screened patients in New Mexico, demonstrating inclusion criteria and without any exclusion criteria, and who wish to receive POCT and therapy, if appropriate. Proper personal protective equipment (PPE) will be worn when performing the GAS POCT, for the protection of the patient and the certified prescribing pharmacist. A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.

ii. The patient's current inclusion and exclusion will be evaluated by the certified prescribing pharmacist performing POCT, using the appropriate FDA-approved POCT.

iii. The following patient information will be obtained: assessment for swollen or tender lymph nodes and tonsillar exudates, temperature, weight (for patients <18 years of age), medical history, current medications, and known drug allergies, by the certified prescribing pharmacy performing POCT.

Patient Inclusion Criteria: Must meet **ALL** of the following:	Patient Exclusion Criteria: Excluded for **ANY** of the following:
1. Positive GAS POCT	1. Patients $\leq$ 3 years of age 2. Negative GAS POCT

2. Presence of signs/symptoms consistent with GAS pharyngitis (i.e., fever, sore throat, painful swallowing, fever, headache, red and swollen tonsils, white patches or pus on tonsils, small red spots on the back roof of the mouth, swollen or tender cervical lymph nodes) 3. Centor score ≥1	3. Symptoms not consistent with GAS pharyngitis 3. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis 5. Immunocompromised state (malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS 6. Clinically unstable, based on the judgement of the certified prescribing pharmacist 7. Centor Score of <1

v. The prescription will be written for an appropriate supply of GAS pharyngitis antimicrobial therapy, consistent with the recommended and prevailing evidence-based guidelines, with no additional refills.[4]

vi. All patients eligible to receive GAS pharyngitis antimicrobial therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

vii. All patients who have a positive POCT result and eligible for GAS pharyngitis antimicrobial therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local provider, or local clinic, for further evaluation.

e. Influenza Antiviral Therapy:

i. This service shall be available to all eligible, appropriately screened patients in New Mexico, who wish to receive POCT, influenza antiviral prophylaxis or influenza antiviral therapy, if appropriate. Proper personal protective equipment (PPE) will be worn when performing the GAS POCT, for the protection of the patient and the certified prescribing pharmacist. A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.

ii. The patient will be evaluated by the certified prescribing pharmacist performing POCT, using the appropriate FDA-approved POCT. This service shall be available to all eligible, appropriately screened patients in New Mexico, demonstrating inclusion criteria and without any exclusion criteria, and who wish to receive POCT and therapy, if appropriate.

iii. The patient's current signs/symptoms, age (patients must be >3 years of age), weight, temperature, oxygen saturation level, medical history, current medications, and known drug allergies will be evaluated by the certified prescribing pharmacist.

iv. If it is determined that influenza is present based on a positive POCT result, the certified prescribing pharmacist will prescribe an influenza antiviral therapy, consistent with the recommended and prevailing evidence-based guidelines, with no additional refills, will follow-up with the patient in 24 to 48 hours for evaluation of signs/symptoms, and will refer the patient to their primary care provider, local provider, or local clinic for recommended laboratory testing and follow-up, if appropriate.[8,9]

v. All patients, eligible to receive influenza antiviral therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

vi. All patients eligible for influenza antiviral therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local provider, or local clinic, for further evaluation.

vii. If it is determined that the POCT is negative, and there is a high index of suspicion for influenza, the certified prescribing pharmacist will refer the patient to their primary care provider, local provider, or local clinic for further medical assessment and follow-up, if appropriate.

XIII. FORMULARY:

a. **HIV PEP Therapy:**

i. nPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + either Raltegravir 400mg twice daily or Dolutegravir 50mg once daily[2,10]

ii. oPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + Raltegravir 400mg twice daily[2,10,11]

iii. Any preferred FDA-approved, CDC-recommended PEP regimens [1,2]

iv. Any NMDOH recommended PEP regimen [2]

b. **COVID-19 FDA-Approved Emergency Use Authorization COVID-19 Therapy:**

i. FDA-approved COVID-19 or EUA therapy, yet to be determined and upon Board of Pharmacy, Medicine, and Nursing, approval and availability.

ii. Intravenous medications are excluded

iii. CDC preventable disease vaccinations are not covered in this protocol, and can be found in the **PROTOCOL FOR PHARMACIST PRESCRIBING OF VACCINES, New Mexico Board of Pharmacy Regulation (16.19.26)**[12]

a. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

i. Penicillin VK

ii. Amoxicillin

iii. Cephalexin

iv. Clindamycin
v. Azithromycin
vi. Clarithromycin
vii. Referral required in a patient with a known allergy that interacts or may interact with the dangerous drug(s) in conjunction with the GAS POCT as outlined in the above **Referrals, Section IX**.

b. **Influenza Antiviral Prophylaxis Therapy, and Influenza Antiviral Therapy:**

i. Oseltamivir phosphate
ii. Baloxavir marboxil (excluded for use in influenza antiviral prophylaxis therapy)
iii. Zanamivir
iv. Other FDA-approved antivirals for influenza (with the exclusion of intravenous medications)

XIV. SIDE EFFECTS/SYMPTOMS:

a. **HIV PEP Therapy:**

i. Tenofovir disoproxil fumarate: asthenia, headache, diarrhea, nausea, vomiting, nephrotoxicity
ii. Emtricitabine: rash, hyperpigmentation/skin discoloration
iii. Raltegravir: insomnia, nausea, fatigue, headache, skin and hypersensitivity reactions
iv. Dolutegravir: insomnia, headache
v. Other side effects: may require referral to primary care provider or local HIV clinic

b. **COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 Therapy:**

i. Refer to package insert of FDA or EUA approved therapy or primary literature.
ii. Other side effects: may require referral to primary care provider or local clinic

c. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

i. Diarrhea
ii. Nausea
iii. Vomiting
iv. Other side effects: may require referral to primary care provider or local clinic

d. **Influenza Antiviral Prophylaxis Therapy, and Influenza Antiviral Therapy:**

i. Oseltamivir phosphate and baloxavir marboxil: abdominal pain, nausea, vomiting, diarrhea, and headache
ii. Zanamivir: sore throat, cough, nasal symptoms, nausea, and diarrhea
iii. Other side effects: may require referral to primary care provider or local clinic

XVII. RECORDS:

a. Consent form
b. Records of notification
c. Billing
d. Prescription order

XVIII. REFERENCES:

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Board of Pharmacy

Chapter 855

Division 20
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:

(1) Continuation of therapy (v. 06/2021)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v. 12/2021); and

(d) COVID-19 Antigen Self-Test Protocol (v. 12/2021); and

(e) COVID-19 Antiviral Protocol (v. 10/2022).

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

(b) Male and female condoms (v. 06/2021);

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. 06/2022);

(d) Travel Medications Protocol (v. 06/2021);

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/2021); and

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 6/2022).

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649
History:
BP 56-2022, amend filed 12/20/2022, effective 02/01/2023
BP 44-2022, temporary amend filed 10/17/2022, effective 10/17/2022 through 04/14/2023
BP 31-2022, amend filed 06/15/2022, effective 06/16/2022
BP 16-2022, amend filed 04/20/2022, effective 04/20/2022
BP 34-2021, temporary amend filed 12/10/2021, effective 12/10/2021 through 06/07/2022
BP 31-2021, amend filed 12/10/2021, effective 12/10/2021

BP 22-2021, temporary amend filed 09/01/2021, effective 09/01/2021 through 02/27/2022
BP 18-2021, amend filed 06/15/2021, effective 06/15/2021
BP 96-2020, amend filed 12/23/2020, effective 12/23/2020
BP 85-2020, amend filed 08/26/2020, effective 08/27/2020
BP 7-2019, amend filed 10/15/2019, effective 10/16/2019
BP 5-2018, adopt filed 10/18/2018, effective 10/18/2018

Please use this link to bookmark or link to this rule.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
  - Utilize the standardized PrEP Provider Fax (pg.10)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you want to start or continue PrEP?
2. Do you sexually partner with men, women, transgender, or non-binary people?
3. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
4. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
5. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
6. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
7. Do you inject drugs?
8. Are you in a relationship with an HIV-positive partner?
9. Do you exchange sex for money or goods? (includes paying for sex)
10. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, general flu-like symptoms?	□ yes □ no
3. When was your last possible HIV exposure?	□ < 72 hrs ago □ 72 hrs - 2 weeks ago □ 2 – 4 weeks ago □ > 4 weeks ago
4. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
5. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__

6. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
7. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
8. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
9. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. o I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Patient requests PrEP	• Patient may not be comfortable sharing detailed sexual history per CDC PrEP guidelines, if a patient requests PrEP, the recommendation is to prescribe it regardless of identified HIV exposure risk.
2. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
3. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
4. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
5. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
6. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
7. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
8. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
9. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
10. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ yes □ *no*

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing. Order lab at initial intake and every 90 days thereafter.			
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing. Order lab at initial intake and every 90-180 days depending on risk.			
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician. Confirmation of being fully vaccinated for hepatitis B via ALERT or medical record may meet criteria for negative Hepatitis B surface antigen. If records of vaccination are not available, order lab at initial intake only.			
• *Hepatitis C antibody (recommended, optional):*	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive antibody indicates exposure to Hepatitis C virus. The pharmacist will refer this person for confirmatory testing and treatment. It is permissible to proceed with PrEP prescribing in this scenario. If planning to monitor for Hep C, order lab at initial intake and at least annually thereafter.			
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment. Order lab at initial intake and every 90-180 days depending on risk.			
• Renal function (CrCl): SCr _____mg/dL	____/____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.* Order lab at initial intake and annually thereafter; if over 50 years old and on emtricitabine/tenofovir DF (Truvada) PrEP order every 6 months.			
• Signs/symptoms of acute retroviral syndrome AND potential HIV exposure in the last 4 weeks AND not on PrEP? □ *Present* □ Not Present □ Yes			
• Exposure risk less than 72 hours ago? □ *Yes* □ No			

2. Is HIV ab/ag 4th gen test resulted? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: Do NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, do NOT prescribe PrEP, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3a. If initial visit: Are syphilis, gonorrhea, chlamydia, Hepatitis B serologies (if no documentation of complete vaccination), and serum creatinine resulted? □ **yes** □ ***no***

- If yes, RPH may prescribe up to a 90 day supply of PrEP. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP for up to a 30 day supply and the patient needs to complete all required labs and bring them in within 30 days before next refill. Proceed to next section: Medical History.

→ *See next page for follow-up visit lab requirements and sample language for reactive (indeterminate) HIV and STI tests.*

3b. If follow-up visit: Are required follow-up labs resulted? □ **yes** □ ***no***

- □ Every 90 days- HIV
- □ Every 90-180 days- Syphilis/Treponemal antibody and Gonorrhea/Chlamydia; Renal function if > 50 yrs old and on emtricitabine/tenofovir DF (Truvada)
- □ Annually - Renal function

- If yes, RPH may prescribe PrEP. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Symptoms of acute retroviral syndrome in last 4 weeks □ *yes* □ no	• Could have acute HIV with negative screening HIV Ag/Ab result. • Order HIV RNA and/or refer to PrEP provider or Infectious Disease provider for further evaluation.
3. Exposure risk was < 72 hrs ago □ *yes* □ no	• Screen for eligibility for PEP (see OBOP Protocol for PEP Prescribing) OR refer to urgent care or ED for further evaluation and possible PEP initiation. • If exposure 72 hours – 2 weeks ago, defer testing and PrEP until at least 2 weeks post exposure and proceed with PrEP according to the result.
4. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
5. Presence of Hepatitis C exposure *Needs Referral:* □ *yes* □ no	• People with HepC exposure must be referred to primary care or other appropriate community health outreach organization (e.g. HIV Alliance, Cascade AIDS Project, Eastern Oregon Center for Independent Living). Pharmacist may proceed with prescribing PrEP.
6. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Truvada is approved for patients with a CrCl >60mL/min. • Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
7. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
	CONSIDERATIONS
8. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
9. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to OAR 855-019-0280.
10. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. • Truvada is preferred due to better data in these populations.

4. Are One or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. • Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. • Only Truvada is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Truvada
NSAID use • If patient is male or a male to female transgender woman, consider Descovy	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Descovy	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available.

PrEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____

_____

_____

_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• Hepatitis B surface antigen:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Hepatitis C antibody:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	
• Renal function (CrCl): ☐ CrCl >60mL/min	____/____/_____ ☐ CrCl 30mL/min - 60mL/min	_____ mL/min ☐ *CrCl <30mL/min*	☐ *Yes*
• Signs/symptoms of acute retroviral syndrome AND potential HIV exposure in the last 4 weeks AND **not** on PrEP?		☐ *present* ☐ not present	☐ *Yes*
• Exposure risk less than 72 hours ago?		☐ yes ☐ no	☐ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PEP Patient Intake Form (pg. 2)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
  - Utilize the standardized PEP Patient Informational Handout (pg. 7)
  - Utilize the standardized PEP Provider Fax (pg. 8)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

PLUS

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
- Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

PEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

End HIV Oregon Toolkit:
HIV Pre-Exposure Prophylaxis (PrEP) Coverage Guide

November 2021

Purpose

Access to PrEP is a key component of Oregon's End HIV Oregon campaign. The state of Oregon funds our local health authorities and some community-based organizations to promote PrEP use and assist with PrEP navigation services. This guide is designed to help anyone interested in supporting people who want access to HIV Pre-Exposure Prophylaxis, commonly known as PrEP, including health providers and people working to end HIV in Oregon. Whether you're are a pharmacist considering prescribing PrEP to customers or a prevention specialist helping community members navigate medical care or insurance systems, we have compiled the basic information and resources you need to answer people's questions, help them find a provider, and figure out how to access the right medications. Read further for brief information on what PrEP is, who it is for, information on statutory and regulatory requirements regarding its use, information on insurance and patient assistance options.

What is PrEP?

PrEP, or pre-exposure prophylaxis, is a medication taken to reduce the chances of getting HIV. Oral medications FDA approved for PrEP include TDF/FTC (brand name Truvada® or a generic equivalent) and TAF/FTC (brand name Descovy®). PrEP is taken once daily as an oral pill and is most effective when taken consistently at the same time each day. An injectable version of PrEP, called Apretude (cabotegravir extended-release injectable suspension) was just approved by the FDA in December 2021. The US Preventive Services Task Force (USPSTF) issued a Grade A recommendation for PrEP for the prevention of HIV transmission, in combination with behavioral counseling, for people at increased vulnerability of contracting HIV. Read further or visit the CDC's website on PrEP for more information on who should consider taking PrEP.

When taken as directed, PrEP can reduce the risk of getting HIV through sex by more than 99% and can reduce the risk of getting HIV among people who inject drugs by up to 74%.

PrEP is one more tool to reduce a person's risk of acquiring HIV, along with viral suppression among people living with HIV, talking to partners about one's HIV status, and consistently using condoms and lubricants. PrEP does not provide protection against other sexually transmitted infections (STIs) or pregnancy.

PrEP navigation services are available in all 36 Oregon counties. There are currently over 300 Oregon providers listed in the Oregon PrEP Provider Directory.

PrEP navigation services are available here in Oregon and often include:

- PrEP education and counseling
- Peer support and advocacy
- Follow-ups and check-ins about PrEP
- Connections to PrEP providers
- Help with health insurance or payment assistance options

Patients on PrEP should be seen by their provider every three months to test for HIV and other STIs. Additional testing guidelines for people on PrEP can be found on pages 3 and 4.

PrEP is a key tool in the prevention pillar of Oregon's End HIV strategy. Our vision is that 100% of Oregonians most in need of PrEP have access to it.

Who is PrEP for?

PrEP is for anyone who is HIV negative and may be at increased vulnerability for acquiring HIV. Certain medications may be recommended based on personal factors; ideally a qualified provider will discuss a patient's specific medical history and life circumstances to determine which medication is right for them.

Is PrEP safe?

According to the CDC, PrEP is both safe and effective in lowering a person's risk of acquiring HIV. While some people experience side effects like diarrhea, nausea, headache, fatigue, and stomach pain, these side effects usually go away with time. Patients experiencing side effects should notify their provider right away so they can discuss strategies to mitigate them and so they can be monitored. In rare instances people may not be able to get past side effects and PrEP may not be an option for them at this time. In these cases, discussing harm reduction strategies is advised. For more information on side effects, check out: https://prepdaily.org/what-are-the-side-effects-of-prep/.

Our Vision:
100% of Oregonians most in need of PrEP, a daily pill to prevent HIV, have access to it.
End HIV Oregon

PrEP Medications

There are currently two FDA approved medications for oral medications for PrEP: TDF/FTC (brand name Truvada® or a generic equivalent) and TAF/FTC (brand name Descovy®). The FDA recently approved cabotegravir extended-release injectable suspension (Apretude) as an injectable form of PrEP.

- Truvada is a brand name for a PrEP medication for all people who may be at increased vulnerability for acquiring HIV through sex or injection drug use
- A generic equivalent to Truvada, Emtricitabine and Tenofovir Disoproxil Fumarate, is also FDA-approved and broadly available.
- Descovy is for people who may be at increased vulnerability for acquiring HIV through sex, except for people assigned female at birth who are at increased vulnerability for getting HIV from vaginal sex. Descovy is also not recommended for people who inject drugs (PWID) or people who use on demand dosing.
- Apretude is an injectable form of PrEP which is given first in two initiation injections given one month apart, and then injections every two months. Apretude is for sexually active men, women, and transgender persons with indications for PrEP use.

PrEP Services

According to the CDC Guidelines, "**PrEP should be considered part of a comprehensive prevention plan that includes a discussion about adherence to PrEP, condom use, other sexually transmitted infections (STIs), and other risk reduction methods.**"[1] HIV testing is required to confirm that patients do not have HIV infection when they start taking PrEP. The following tables list ancillary services and testing that accompany PrEP by timeline, for oral or injectable PrEP (as indicated), and are typically covered by insurance.

For Oral PrEP, provide the following services:	
Initial prescription and initiation of PrEP	▪ Routine office visit for screening, patient education, and identification of contraindications ▪ Initial HIV test and other lab screening including STIs and pregnancy ▪ Offer vaccinations such as Hepatitis A or B and Human Papillomavirus (HPV)
Follow-up visits every 3 months to provide:	▪ Test for HIV ▪ Provide medication adherence and behavioral risk reduction support ▪ Access to clean needle/syringes and drug treatment services for PWID ▪ Additionally, for ○ All people at risk for STIs: screen for bacterial STIs based on anatomic site of exposure ○ People with reproductive potential: test for pregnancy; and ○ PWID: assess access to sterile needles/syringes and to drug treatment services
Follow-up visits every 6 months to provide:	▪ Assess renal function for patients aged $\geq$ 50 or who have an eCrCl<90 ml/min at PrEP initiation ▪ Additionally, for ○ All people at risk for STIs: screen for bacterial STIs based on anatomic site of exposure ○ People with reproductive potential: test for pregnancy; and ○ PWID: assess access to sterile needles/syringes and to drug treatment services
Follow-up visits every 12 months to provide:	▪ Assess renal function for all patients ▪ Chlamydia screening for heterosexually active women and men ▪ For patients on F/TAF, assess weight, triglyceride, and cholesterol levels.

[1] https://www.cdc.gov/hiv/clinicians/prevention/prep.html

For Injectable PrEP, provide the following services:	
Initial prescription and initiation of PrEP	▪ Routine office visit for screening, patient education, and identification of contraindications ▪ Initial HIV test and other lab screening including STIs and pregnancy ▪ Offer vaccinations such as Hepatitis A or B and Human Papillomavirus (HPV)
Follow-up visit 1 month after first injection	▪ Test for HIV
Follow-up visits every 2 months (beginning with the third injection – month 3) to provide:	▪ Test for HIV ▪ Provide medication adherence and behavioral risk reduction support ▪ Access to clean needle/syringes and drug treatment services for PWID
Follow-up visits every 4 months (beginning with the third injection – month 3) to provide:	▪ Additionally, for ○ All people at risk for STIs: screen for bacterial STIs based on anatomic site of exposure ○ People with reproductive potential: test for pregnancy; and ○ PWID: assess access to sterile needles/syringes and to drug treatment services
Follow-up visits every 6 months (beginning with the fifth injection – month 7) to provide:	▪ Additionally, for ○ All people at risk for STIs: screen for bacterial STIs based on anatomic site of exposure ○ People with reproductive potential: test for pregnancy; and ○ PWID: assess access to sterile needles/syringes and to drug treatment services
Follow-up visits every 12 months to provide:	▪ Assess desire to continue injections for PrEP ▪ Chlamydia screening for heterosexually active women and men

Finding a PrEP Provider

If you or someone you know is interested in exploring PrEP, there are over 300 PrEP Providers statewide who are available to prescribe it. Explore this growing list at: https://www.oraetc.org/prep-provider-list. In addition, some pharmacists are now prescribing PrEP.

Patient Assistance Options

Oregonians on Medicaid – locally known as the Oregon Health Plan (OHP) - are eligible for PrEP at no cost.

Oregonians with private insurance – As of late 2021, most insurance plans cover PrEP and the necessary screenings, visits, and labs (initial and ongoing) at no cost to the patient. This makes PrEP widely available to more people, including many who formerly found PrEP prohibitive because of high co-pays and deductibles or exorbitant out-of-pocket costs for PrEP.

Ready, Set, PrEP. This program makes PrEP medication available at no cost to those who don't have health insurance coverage for prescription drugs, have taken a HIV test and received a negative result before starting the program, live in the United States including tribal lands or territories, and who have a prescription for PrEP. While Ready, Set, PrEP covers the cost of medications, it does not cover labs. Click here for more information: https://readysetprep.hiv.gov/

PrEP Availability and Coverage: Statutory and Regulatory Impacts

In June 2019 the U.S. Preventive Services Task Force (USPSTF) issued a final "Grade A" recommendation that directed clinicians to offer PrEP with "effective antiretroviral therapy to persons who are a high risk of HIV acquisition." The recommendation covers adolescents, adults, and pregnant people. You can find more information in English here or in Spanish here.

Most insurers were not required to abide by the 2019 USPSTF Grade A recommendation for PrEP until January 2021. Also, the requirement was initially confined to the cost of the medication, not the office visits and costs for screening.

That recommendation triggered a statutory coverage requirement for health plans. Accordingly, plans and insurers would be required to cover PrEP consistent with the USPSTF recommendation without cost sharing beginning on or after one year from the issue date of the recommendation (in this case, plan or policy years beginning on or after June 30, 2020).

What happened in 2021 that impacted insurance coverage for PrEP?

On July 19, 2021, the Centers for Medicare and Medicaid Services (CMS), along with the Department of Labor and the Department of the Treasury, issued guidance directing health insurers that they have 60 days to comply with the mandate to cover PrEP with no cost sharing – including for the drug itself and, crucially, for clinic visits and lab tests. This means insurers must not charge copays, coinsurance, or deductible payments for the initial visit or the quarterly clinic visits and accompanying lab tests required to maintain a PrEP prescription.

This was a significant expansion to the original guidance. The regulatory authority for this type of mandate is Section 2713 of the Affordable Care Act (ACA). Under the ACA, private health

plans, except for those plans that maintain "grandfathered" status,[2] must provide coverage for a range of preventive services and may not impose cost sharing (such as copayments, deductibles, or co-insurance) on patients receiving such services. Nearly all private plans, including employer plans and those offering coverage through ACA marketplaces, are required to provide PrEP free of patient cost sharing.[3]

Insurance Plans and PrEP Coverage

Most insurance plans and state Medicaid programs cover PrEP and there are other programs that provide aid with free or reduced costs. In addition, with the 2019 USPSTF recommendation and the CMS guidance in 2020, plans and insurers cannot use reasonable medical management techniques to restrict the frequency of these services if the frequency is specified in the PrEP recommendation. That means prior authorization or other "reasonable" management techniques cannot be used. However, plans and insurers can use reasonable medical management techniques with respect to PrEP coverage in some circumstances.

Plans and insurers can, for instance, opt to cover only the generic version of PrEP without cost sharing while requiring cost sharing for branded versions (e.g., Truvada). This would encourage use of the generic drug over more expensive branded drugs. However, plans and insurers that do so must have an accommodations process to waive cost sharing when a patient cannot use the generic drug for medical reasons.

Plans and insurers must also have an easily accessible, transparent, and expedient exceptions process for the patient or provider to request a different drug. In the context of PrEP, this process should enable access to PrEP medication on the same day that a person receives a negative HIV test or decides to start taking PrEP.

Oregon Health Plan: The costs for PrEP and all services related to PrEP, are covered at no cost to the enrollee. There will not be a statement sent to the OHP member's home and the services are completely confidential.

Medicare:

Unlike Oregon's commitment to zero cost sharing for people eligible for OHP, Medicare does not have that kind of protection unless you are eligible for both OHP and Medicare. If you are "dually eligible" you will likely have no cost sharing for PrEP coverage.

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[2] The Affordable Care Act (ACA) exempts certain health plans that were in effect when the law was passed, referred to as grandfathered plans, from some standards in the law, including the requirement to cover preventive services without cost sharing, have an external appeals process, or comply with the new benefit and rating provisions in the small group market. In 2019, 22% of firms offering health benefits offer at least one grandfathered health plan, and 13% of covered workers are enrolled in a grandfathered plan. https://www.kff.org/report-section/ehbs-2019-section-13-grandfathered-health-plans/

[3] For more information on insurance plans and impact of the ACA see: https://www.kff.org/report-section/ehbs-2019-section-13-grandfathered-health-plans/, https://www.associationhealthplans.com/group-health/what-is-erisa-health-insurance/

Understanding Medicare coverage is complex and can be confusing. Medicare Part D is a voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans approved by the federal government. You can choose to enroll in either a stand-alone prescription drug plan (PDP) to supplement traditional Medicare or a Medicare Advantage prescription drug plan (MA-PD) that cover all Medicare benefits including drugs.

Out-of-pocket costs can still be substantial when relying on Part D coverage. This is because when the Part D benefit was created in 2003, a coverage gap (also called the donut hole) was created to incentivize the use of generics and control overall benefit costs. The Part D standard benefit has several phases:

Benefit Design	2022 Threshold	Financial Responsibility
Deductible	$480	Enrollee 100% of costs
Initial Coverage Phase	$4,430 Limit	Enrollee 25% and PDP Plan 75%
Coverage Gap (Donut Hole)	$4,431-$10,689	Enrollee 25%/Manufacturer 70%/Plan 5%*
Catastrophic Coverage	$10,690	Enrollee 15%/Federal Government 80%

*Manufacturer and Plan financial responsibility in the gap varies for brand-name and biosimilar drugs compared to generics.

Therefore, if you are not eligible for both OHP and Medicare, you will probably experience cost sharing. There are still many options to minimize your costs including enrolling in a Medicare Advantage plan that includes Part D or a stand-alone Part D plan (also called a Prescription Drug Plan or PDP.)

All Medicare Advantage (Medicare Part C) and Prescription Drug Plans (Medicare Part D) are required to cover antiretrovirals like Truvada but many plans have high levels of cost sharing for this drug depending on the Plan's formulary. The amount individuals pay for Truvada depends on their plan, how the drug is classified within the plan's tier system, and your eligibility for any programs that could help lower costs.

At Medicare.gov there is a user-friendly tool that allows you to enter your prescription drug regimen and compare out-of-pocket costs across Medicare Advantage plans and stand-alone Part D plans. Considering the unsubsidized cost of PrEP, this step could minimize out-of-pocket costs.

It's important to consider Medicare Advantage or Medicare Supplement plan costs carefully when choosing a prescription drug plan. A 2020 analysis [4] showed that Medicare beneficiaries living with HIV often pay higher premiums for plans with low deductibles, and the savings don't always add up. For example, Medicare Part D and Medicare Advantage plans cover the cost of HIV treatment and PrEP, but there is often a co-pay cost which ranges between $13 to $68. Careful evaluation of Medicare Advantage plans, including Prescription Drug plans, should be conducted before selecting a plan.

[4] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764374

In addition to coverage for people who are dually eligible for Medicare and Medicaid, people with low incomes and modest assets are eligible for assistance with Part D plan premiums and cost sharing. Through the Part D Low-Income Subsidy (LIS) program, Extra Help, additional premium and cost-sharing assistance is available for Part D enrollees with low incomes (less than 150% of poverty, or $19,320 for individuals/$26,130 for married couples in 2021) and modest assets (less than $14,790 for individuals/$29,520 for couples in 2021.)

Pharmacist Prescribed PrEP/PEP

Here in Oregon, pharmacists can play a key role in ensuring people have access to PrEP because they are now allowed to prescribe an initial 90-day supply of PrEP and can be reimbursed by insurers at the same rate as other health care providers. Incidentally, this also applies to prescribing Post-Exposure Prophylaxis (PEP), a medication an individual can take up to 72 hours after exposure to HIV to prevent seroconversion. Seroconversion usually occurs within a weeks of HIV infection and is when HIV antibodies are detectable in the blood. This is possible because of two key pieces of legislation, House Bills 2397 and 2958.

- HB 2397. Passed in 2017, it granted the Oregon Board of Pharmacy the authority to allow pharmacists licensed in Oregon to prescribe, dispense, and administer board-approved drugs and devices in alignment with a standard protocol. Recently, the Board approved PrEP and PEP for prescribing by pharmacists who complete continuing education on HIV prevention medications.[5]
- HB 2958. Signed into law by Governor Kate Brown in June of 2021, this bill requires insurers to reimburse pharmacists for prescribing PrEP and PEP at the same rate they would any other health care provider. It also requires insurers to cover at least one form of PrEP without prior authorization and regardless of whether the pharmacist is in-network. (Some health care providers, such as Kaiser Permanente, are exempt from the prohibition on network restrictions.)

While there are now laws allowing pharmacists to prescribe an initial 90-day supply of PrEP and a financial incentive to do so, there are a few considerations that pharmacists and their employers should consider before moving forward.

Training

The Oregon Board of Pharmacy requires that pharmacists complete a comprehensive training program on the prescribing and dispensing of HIV prevention medications including trauma informed care. While it is up to pharmacists to determine if a training meets the requirements, the Oregon State University College of Pharmacy is in the process of creating a 2-hour online program.

[5] https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Pages/prep-pep.aspx#providers

Pharmacy Participation

Pharmacies will need to evaluate whether they have sufficient staffing, organizational capacity, and adequate physical space to provide the necessary screenings and services to patients in a manner that ensures patient confidentiality. Pharmacists need to have the appropriate patient permission under HIPAA to obtain clinical records from the patient's providers and have the capability to keep the information received secure as required under HIPAA. Pharmacists must ensure the client transitions to an authorized on-going PrEP prescriber, such as a primary care provider, to continue with the PrEP clinical protocols. Additional barriers could include medical billing infrastructure and capacity.

Required Labs for Prescribing PrEP

Prior to prescribing PrEP, a pharmacist must verify all the required laboratory tests for PrEP initiation or ongoing management have been completed and are negative or within range. Please note that a negative HIV test must be completed within a 14-day range prior to prescribing. The Oregon Board of Pharmacy protocol stipulates the following required test:

- HIV ag/ab (4^{th} gen) – every 90 days
- Syphilis/Treponemal antibody – at least every 6 months
- Chlamydia/Gonorrhea (urinalysis, pharyngeal, and/or rectal dependent on patient sexual behaviors) – at least every 6 months
- Hepatitis B surface antigen – frequency not specified by protocol
- Creatinine Clearance – frequency not specified by protocol

If only a negative HIV test result is available, the pharmacist can still prescribe PrEP, however, the patient must complete the necessary labs within 30 days and bring in the results to the pharmacist.[6]

[6] https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Pages/prep-pep.aspx#providers

Common Myths About PrEP

Here are some common myths your clients or patients might have about PrEP and some information to help dispel them.

Myth #1: I don't have insurance so I can't afford PrEP.

FALSE! Fortunately, there is an option to access the PrEP medication at an affordable cost even if you don't have insurance coverage. Ready, Set, PrEP is a program that makes PrEP medication available at no cost specifically for those that do not have health insurance coverage for prescription drugs. You can find out more about eligibility by visiting their website at: https://readysetprep.hiv.gov/.

Uninsured clients should consider seeking services at Federally Qualified Health Centers or other community clinics (Planned Parenthood) to offset the out-of-pocket costs for the office visits and laboratory screenings. Not only are these providers less expensive, but they can provide on-going follow up care, including authorizing additional 90-day supplies, that an Emergency Department is not designed to provide. Cover All People, a law passed in the 2021 Oregon Legislature, expands coverage through the Oregon Health Plan (OHP) to adults who are eligible except for their documentation status. As the law is rolled out, beginning July 1, 2022, specific groups of individuals will qualify to receive full OHP benefits, including PrEP. Consult a PrEP navigator and/or https://www.oregon.gov/oha/HSD/OHP/Pages/index.aspx to stay abreast of updates to Cover All People coverage for undocumented adults who qualify for OHP.

Myth #2: I have insurance, but I won't be able to afford the copays for the medication or all the other lab tests and ongoing medical visits.

FALSE! Thanks to the US Preventive Services Task Force (USPSTF) and the Affordable Care Act (ACA), insurance plans are now required to cover the cost of PrEP medications and the medical visits and labs associated with PrEP at no cost to the patient! What this means is that your visits and prescriptions should be covered in full, with no copays to you. If your insurance plan is exempt from USPSTF and ACA requirements, consider seeking services from a community clinic such as an FQHC or Planned Parenthood. This requirement is new as of late 2021, so if you tried to get PrEP previously and were faced with large copays or other expenses, try again! You can also contact a PrEP navigator who is trained to assist with insurance and coverage challenges. You can find a PrEP navigator through Cascade AIDS Project here or HIV Alliance here.

Myth #3: I want to get PrEP, but I am concerned that if I do, my medical chart will make it look like I participate in behaviors that put me at increased risk of HIV.

FALSE! There are many reasons why someone might want to use PrEP. Be forthcoming with your provider about your health and wellness – or find a provider with whom you can talk freely about behaviors or circumstances that may have increased your chances of contracting HIV. Anything you disclose to your provider is confidential. It may be useful to seek out a healthcare provider who is knowledgeable about LGBTQ health and/or HIV or a LGBTQ-friendly clinic such as Planned Parenthood. There are more than 300 medical providers across the state

of Oregon who asked to be listed on the PrEP Provider Directory – indicating that they are open to discussing and providing PrEP. https://www.oraetc.org/prep-provider-list

Myth #4: I am on my parents' insurance so they will find out if I am on PrEP.

FALSE! In Oregon, minors of any age can access family planning/sexual and reproductive health services without parental consent.[7] This means that the provider will not inform your parents you are accessing PrEP. That said, depending on your insurance, an explanation of benefits (EOB) letter may be sent to your home outlining the services you received. Oregon law guarantees you the right to have protected health information sent directly to you instead of to the person who pays for your health insurance plan (the primary account holder). You can have this information shared with you directly through several different methods including email, telephone, or at a different mailing address. More information, including the Request for Confidential Communication form, can be found here.

The Oregon Health Plan (OHP) does not send EOBs so if you have OHP, you don't need to worry about one being sent to your home even if you are enrolled with a CCO.

Myth #5: I don't currently have legal documentation to reside in the US and so I can't qualify for assistance to get PrEP.

FALSE! Ready, Set, PrEP is a program that provides free access to PrEP medications to thousands of people living in the United States, including tribal lands and territories. Ready, Set, PrEP is specifically for people who don't have health insurance coverage. Please note that Ready, Set, PrEP covers the cost of medication but does not cover the cost of labs or office visits. If this is cost prohibitive, consider going to a community clinic like Planned Parenthood or a Federally Qualified Health Center. As previously mentioned, Cover All People expands health coverage through the Oregon Health Plan (OHP) to adults who are eligible except for their documentation status. As the law is rolled out, beginning July 1, 2022, specific groups of individuals will qualify to receive full OHP benefits, including PrEP. Consult a PrEP navigator and/or https://www.oregon.gov/oha/HSD/OHP/Pages/index.aspx to stay abreast of updates to Cover All People coverage for undocumented adults who qualify for OHP.

Myth #6: My health plan might not cover PrEP or might only cover a portion of it, making it too expensive for me.

FALSE! If your health plan is exempt from the USPSTF and ACA requirements, there are several patient assistance programs through the manufacturers, Gilead's Advancing Access Program, or publicly funded assistance programs such as Ready, Set, PrEP.

[7] https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/YOUTH/Documents/minor-rights.pdf

Myth #7: My insurance company still requires prior authorization for PrEP and haven't removed copays or cost sharing for PrEP. There doesn't seem to be a realistic pathway to take advantage of PrEP unless you are rich.

FALSE! Oregon Health Plan clients will not face prior authorization requirements or copays/cost sharing for PrEP. If your insurance company is still requiring prior authorizations and charging copays/cost sharing, you have appeal rights to remove these barriers. Many insurance plans will cover an initial dispense until your appeal is resolved. Again, there are other options available, but most insurance coverage will not require these types of potential barriers. You can also ask your primary care provider to appeal the insurance plan's policies and practices. Finally, connecting with a PrEP Navigator or the state insurance commissioner is also an option.

Myth #8: I already started PrEP but stopped taking it and it won't be authorized again.

FALSE! Plans and insurers cannot restrict the number of times an individual may start PrEP.

Additional Resources on PrEP

CDC
https://www.cdc.gov/hiv/basics/prep.html

CDC Guidelines on PrEP
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

CDC Guidelines for PrEP – Clinical Providers' Supplement
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf

Descovy Provider Information Page:
https://www.descovyhcp.com/prep-guidelines

Fact sheet on Pharmacist Prescribed PrEP
https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Pages/prep-pep.aspx#providers

FDA Announcement on Injectable PrEP
https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention

GlaxoSmithKline Information on Apretude (cabotegravir or injectable PrEP)
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF#page=36

HIV.gov
https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis

NASTAD Fact Sheet on PrEP
https://www.nastad.org/sites/default/files/resources/docs/nastad-prep-coverage-brief-on-prep-services.pdf

OHA End HIV and PrEP Infographic

English:
https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Documents/PrEP%20and%20PEP/PrEP_Grade_A_English.pdf

Spanish:
https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Documents/PrEP%20and%20PEP/PrEP_Grade_A_Spanish.pdf

O'Neil Law Georgetown reference
https://oneill.law.georgetown.edu/wp-content/uploads/2021/09/Quick-Take-Ensuring-Compliance-With-New-Federal-USPSTF-PrEP-Guidance.pdf

Oregon AIDS Education & Training Center (AETC)
https://www.oraetc.org/prep

PrEP Navigation Services

Cascade AIDS Project: https://www.capnw.org/prep/
HIV Alliance: https://hivalliance.org/prevent/prevention-meds/#pep-prep

Truvada Provider Information Page
https://www.truvadahcp.com/

US Preventive Services Task Force- recommendation of PrEP
https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis

PHARMACY PRACTICE MODIFICATIONS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Norman K. Thurston

Senate Sponsor: Curtis S. Bramble

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- amends the definition of the practice of pharmacy to include issuing a prescription for certain prescription drugs and devices;
- defines the types of prescription drugs and devices that may be prescribed by a pharmacist; and
- authorizes the Division of Occupational and Professional Licensing to make rules to implement the provisions of this bill.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2019, Chapter 343

ENACTS:

58-17b-627, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-102** is amended to read:

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C. Sec. 351 (2003).

(3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.

(b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time

beyond which the contents of the prescription are not recommended to be used.

(7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.

(9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.

(11) "Class B pharmacy":

(a) means a pharmacy located in Utah:

(i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and

(ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and

(b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

(ii) pharmaceutical administration and sterile product preparation facilities.

(12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.

(13) "Class D pharmacy" means a nonresident pharmacy.

(14) "Class E pharmacy" means all other pharmacies.

(15) (a) "Closed-door pharmacy" means a pharmacy that:

(i) provides pharmaceutical care to a defined and exclusive group of patients who have

access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company; or

(ii) engages exclusively in the practice of telepharmacy and does not serve walk-in retail customers.

(b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

(17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and

strengths prescribed by a practitioner; or

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(19) "Confidential information" has the same meaning as "protected health information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.

(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.

(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.

(23) "Dispensing medical practitioner" means an individual who is:

(a) currently licensed as:

(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(iii) a physician assistant under Chapter 70a, Utah Physician Assistant Act;

(iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or

(v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice for an optometrist; and

(b) licensed by the division under the Pharmacy Practice Act to engage in the practice of a dispensing medical practitioner.

(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.

(25) "Distribute" means to deliver a drug or device other than by administering or dispensing.

(26) (a) "Drug" means:

(i) a substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(ii) a substance that is required by any applicable federal or state law or rule to be dispensed by prescription only or is restricted to administration by practitioners only;

(iii) a substance other than food intended to affect the structure or any function of the body of humans or other animals; and

(iv) substances intended for use as a component of any substance specified in Subsections (26)(a)(i), (ii), (iii), and (iv).

(b) "Drug" does not include dietary supplements.

(27) "Drug regimen review" includes the following activities:

(a) evaluation of the prescription drug order and patient record for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication of therapy;

(c) evaluation of the prescription drug order and patient record for the following interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease; and

(iv) adverse drug reactions; and

(d) evaluation of the prescription drug order and patient record for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(28) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.

(29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(30) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to inpatients of a general acute hospital or specialty hospital licensed by the Department of Health under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(32) "Legend drug" has the same meaning as prescription drug.

(33) "Licensed pharmacy technician" means an individual licensed with the division, that may, under the supervision of a pharmacist, perform the activities involved in the technician practice of pharmacy.

(34) "Manufacturer" means a person or business physically located in Utah licensed to be engaged in the manufacturing of drugs or devices.

(35) (a) "Manufacturing" means:

(i) the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container; and

(ii) the promotion and marketing of such drugs or devices.

(b) "Manufacturing" includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(c) "Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis.

(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.

(37) "Medication profile" or "profile" means a record system maintained as to drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze the profile to provide pharmaceutical care.

(38) "Misbranded drug or device" means a drug or device considered misbranded under 21 U.S.C. Sec. 352 (2003).

(39) (a) "Nonprescription drug" means a drug which:

(i) may be sold without a prescription; and

(ii) is labeled for use by the consumer in accordance with federal law.

(b) "Nonprescription drug" includes homeopathic remedies.

(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.

(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located outside the state that is licensed and in good standing in another state, that:

(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in this state pursuant to a lawfully issued prescription;

(b) provides information to a patient in this state on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; or

(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

(43) "Patient counseling" means the written and oral communication by the pharmacist

or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of drugs, devices, and dietary supplements.

(44) "Pharmaceutical administration facility" means a facility, agency, or institution in which:

(a) prescription drugs or devices are held, stored, or are otherwise under the control of the facility or agency for administration to patients of that facility or agency;

(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist or pharmacy intern with whom the facility has established a prescription drug supervising relationship under which the pharmacist or pharmacy intern provides counseling to the facility or agency staff as required, and oversees drug control, accounting, and destruction; and

(c) prescription drugs are professionally administered in accordance with the order of a practitioner by an employee or agent of the facility or agency.

(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:

(i) designing, implementing, and monitoring a therapeutic drug plan intended to achieve favorable outcomes related to a specific patient for the purpose of curing or preventing the patient's disease;

(ii) eliminating or reducing a patient's symptoms; or

(iii) arresting or slowing a disease process.

(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a prescribing practitioner.

(46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this state.

(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical facility carrying out the following business activities:

(i) intracompany sales;

(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:

(A) hospitals;

(B) pharmacies;

(C) chain pharmacy warehouses, as defined by division rule; or

(D) other health care entities, as defined by division rule;

(iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, for emergency medical reasons, including supplying another pharmaceutical facility with a limited quantity of a drug, if:

(A) the facility is unable to obtain the drug through a normal distribution channel in sufficient time to eliminate the risk of harm to a patient that would result from a delay in obtaining the drug; and

(B) the quantity of the drug does not exceed an amount reasonably required for immediate dispensing to eliminate the risk of harm;

(iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer; and

(v) the distribution of prescription drugs, if:

(A) the facility's total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales; and

(B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

(48) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

(49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing

who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of the pharmacy and all personnel.

(50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or more years of licensed experience. The preceptor serves as a teacher, example of professional conduct, and supervisor of interns in the professional practice of pharmacy.

(51) "Pharmacy" means any place where:

(a) drugs are dispensed;

(b) pharmaceutical care is provided;

(c) drugs are processed or handled for eventual use by a patient; or

(d) drugs are used for the purpose of analysis or research.

(52) "Pharmacy benefits manager or coordinator" means a person or entity that provides a pharmacy benefits management service as defined in Section 49-20-502 on behalf of a self-insured employer, insurance company, health maintenance organization, or other plan sponsor, as defined by rule.

(53) "Pharmacy intern" means an individual licensed by this state to engage in practice as a pharmacy intern.

(54) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.

(55) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and division rule adopted after consultation with the Board of pharmacy and the governing boards of the practitioners described in Subsection (23)(a).

(b) "Practice as a dispensing medical practitioner" does not include:

(i) using a vending type of dispenser as defined by the division by administrative rule; or

(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as

defined in Section 58-37-2.

(56) "Practice as a licensed pharmacy technician" means engaging in practice as a pharmacy technician under the general supervision of a licensed pharmacist and in accordance with a scope of practice defined by division rule made in collaboration with the board.

(57) "Practice of pharmacy" includes the following:

(a) providing pharmaceutical care;

(b) collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;

(c) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs or devices, provided that the administration of a prescription drug or device is:

(i) pursuant to a lawful order of a practitioner when one is required by law; and

(ii) in accordance with written guidelines or protocols:

(A) established by the licensed facility in which the prescription drug or device is to be administered on an inpatient basis; or

(B) approved by the division, in collaboration with the board and the Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be administered on an outpatient basis solely by a licensed pharmacist;

(d) participating in drug utilization review;

(e) ensuring proper and safe storage of drugs and devices;

(f) maintaining records of drugs and devices in accordance with state and federal law and the standards and ethics of the profession;

(g) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses;

(h) providing drug product equivalents;

(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy technicians;

(j) providing patient counseling, including adverse and therapeutic effects of drugs;

(k) providing emergency refills as defined by rule;

(l) telepharmacy;

(m) formulary management intervention; [~~and~~]

(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 64, Family Planning Access Act[~~.~~]; and

(o) issuing a prescription in accordance with Section 58-17b-627.

(58) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.

(59) "Practice of telepharmacy across state lines" means the practice of pharmacy through the use of telecommunications and information technologies that occurs when the patient is physically located within one jurisdiction and the pharmacist is located in another jurisdiction.

(60) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

(61) "Prescribe" means to issue a prescription:

(a) orally or in writing; or

(b) by telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule.

(62) "Prescription" means an order issued:

(a) by a licensed practitioner in the course of that practitioner's professional practice or by collaborative pharmacy practice agreement; and

(b) for a controlled substance or other prescription drug or device for use by a patient or an animal.

(63) "Prescription device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by or through a person or entity licensed under this chapter or exempt from

licensure under this chapter.

(64) "Prescription drug" means a drug that is required by federal or state law or rule to be dispensed only by prescription or is restricted to administration only by practitioners.

(65) "Repackage":

(a) means changing the container, wrapper, or labeling to further the distribution of a prescription drug; and

(b) does not include:

(i) Subsection (65)(a) when completed by the pharmacist responsible for dispensing the product to a patient; or

(ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for dispensing a product to a patient.

(66) "Research using pharmaceuticals" means research:

(a) conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(b) requiring the use of a controlled substance, prescription drug, or prescription device;

(c) that uses the controlled substance, prescription drug, or prescription device in accordance with standard research protocols and techniques, including, if required, those approved by an institutional review committee; and

(d) that includes any documentation required for the conduct of the research and the handling of the controlled substance, prescription drug, or prescription device.

(67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(68) (a) "Self-administered hormonal contraceptive" means a self-administered hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy.

(b) "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

(c) "Self-administered hormonal contraceptive" does not include any drug intended to induce an abortion, as that term is defined in Section 76-7-301.

(69) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

(70) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

(71) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as those duties may be further defined by division rule adopted in collaboration with the board; and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

(72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(73) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

(74) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

Section 2. Section **58-17b-627** is enacted to read:

58-17b-627. Prescription of drugs or devices by a pharmacist.

(1) Beginning January 1, 2022, a pharmacist may prescribe a prescription drug or device if:

(a) prescribing the prescription drug or device is within the scope of the pharmacist's

training and experience;

(b) the prescription drug or device is designated by the division by rule under Subsection (3)(a); and

(c) the prescription drug or device is not a controlled substance that is included in Schedules I, II, III, or IV of:

(i) Section 58-37-4; or

(ii) the federal Controlled Substances Act, Title II, P.L. 91-513.

(2) Nothing in this section requires a pharmacist to issue a prescription for a prescription drug or device.

(3) The division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) designate the prescription drugs or devices that may be prescribed by a pharmacist under this section, beginning with prescription drugs or devices that address a public health concern that is designated by the Department of Health, including:

(i) post-exposure HIV prophylaxis;

(ii) pre-exposure HIV prophylaxis;

(iii) self-administered hormonal contraceptives;

(iv) smoking cessation; and

(v) naloxone;

(b) create guidelines that a pharmacist must follow when prescribing a prescription drug or device, including guidelines:

(i) for notifying the patient's primary care or other health care provider about the prescription; and

(ii) to prevent the over-prescription of drugs or devices including but not limited to antibiotics;

(c) address when a pharmacist should refer the patient to an appropriate health care provider or otherwise encourage the patient to seek further medical care; and

(d) implement the provisions of this section.

(4) The division shall make rules under Subsection (3) in collaboration with:

(a) individuals representing pharmacies and pharmacists;

(b) individuals representing physicians and advanced practice clinicians; and

(c) (i) if the executive director of the Department of Health is a physician, the executive director of the Department of Health;

(ii) if the executive director of the Department of Health is not a physician, a deputy director who is a physician in accordance with Subsection 26-1-9(4); or

(iii) a designee of the individual described in Subsection (4)(c)(i) or (ii).

(5) Before November 1 of each year, the division, in consultation with the individuals described in Subsection (4), shall:

(a) develop recommendations for statutory changes to improve patient access to prescribed drugs in the state; and

(b) report the recommendations developed under Subsection (5)(a) to the Health and Human Services Interim Committee.

SPENCER J. COX
Governor
DEIDRE M. HENDERSON
Lieutenant Governor

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

MARGARET W. BUSSE
Executive Director
MARK B. STEINAGEL
Division Director

Utah Guidance For Pre-Exposure and Post-Exposure Prophylaxis of HIV

Approved September 28, 2021

In compliance with Utah Code § 58-17b-627 a Utah licensed pharmacist may prescribe a prescription drug or device within the scope of the pharmacist's training and experience pursuant to Utah Admin. Code § R156-17b-627, the Pre-Exposure Self-Screening Patient Intake Form, the Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway and the Pre-Exposure Provider Fax or the Post-Exposure Self-Screening Patient Intake Form, the Post-Exposure Prophylaxis (PEP) Assessment and Treatment Care Pathway, and the Post-Exposure Provider Fax.

(CONFIDENTIAL- Protected Health Information)

Date _____/_____/_____
Legal Name_____
Sex Assigned at Birth (circle) M / F
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL- Protected Health Information)

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. ○ I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Testing: The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test:	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing.			
• Syphilis/Treponemal antibody:	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.			
• Hepatitis B surface antigen:	_____/_____/_____	□ *positive* □ negative	□ *Yes*
Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.			
• Gonorrhea/Chlamydia:	_____/_____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ negative	Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative	Rectal test result: □ *reactive* □ *indeterminate* □ negative	
All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.			
• Renal function (CrCl): SCr _____mg/dL	_____/_____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.*			
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3. Are all required labs are complete? □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History

Sample language for reactive or indeterminate tests:
Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

→ *See next page for sample language for reactive (inderterminate) STI test.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

Utah Department of Health https://ptc.health.utah.gov/local-health-departments/

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Truvada is approved for patients with a CrCl >60mL/min. • Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
4. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
	CONSIDERATIONS
5. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
6. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to Utah Admin Code R156-17b-621
7. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. • Truvada is preferred due to better data in these populations.

4. Are one or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*

If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	**Preferred regimen**
Cis-gender male or male to female transgender woman. • Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. • Only Truvada is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Truvada
NSAID use • If patient is male or a male to female transgender woman, consider Descovy	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Descovy	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available

PrEP Prescription

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification

Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____
Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily for 90 days
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily for 90 days

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Syphilis/Treponemal antibody:	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Hepatitis B surface antigen:	_____/_____/_____	☐ *positive* ☐ negative	☐ *Yes*
• Gonorrhea/Chlamydia:	_____/_____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	
• Renal function (CrCl): ☐ CrCl >60mL/min	_____/_____/_____ ☐ CrCl 30mL/min - 60mL/min	_____ mL/min ☐ *CrCl <30mL/min*	☐ *Yes*
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	☐ *present*	☐ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	☐ *yes*	☐ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacy monitoring of HIV PrEP:

- The pharmacy prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialist and is available every day at: (855) 448-7737. For Information about PrEP, please visit the CDC website.

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____

Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

PLUS

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
- Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

***** For any child who is currently in danger of serious injury, or is suspected to be currently in danger of serious injury, please contact Utah Child Protective Services @ 1-855-323-3237.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

PEP Prescription

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Patient Information
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the- counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

Adopted: 9/24/2021
Effective Date: 12/22/2021

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*****Note: A pharmacy may create and use an electronic format for the PEP Patient Intake Form, PEP Assessment and Treatment Care Pathway, and PEP Patient Informational Handout, and PEP Provider Fax Notification if the information is identical to the forms included in this protocol.

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

1. Is the patient less than 18 years old?		Notes:
☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic	☐ No: Go to #2	
2. Was the patient a survivor of sexual assault?		Notes:
☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**	☐ No: Go to #3	
3. Is the patient known to be HIV-positive?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).	
4. What time did the exposure occur?		Notes:
☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.	☐ ≤72 hours ago: go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
☐ Yes: Go to #6	☐ No: Go to #7	
6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:		Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.
Please check any/all that apply: ☐Blood ☐Semen ☐Vaginal secretions ☐Rectal secretions ☐Breast milk ☐Any body fluid that is visibly contaminated with blood If any boxes are checked, go to #9.	Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*): ☐Urine ☐Nasal Secretions ☐Saliva ☐Sweat ☐Tears ☐None of the above Go to #7	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
☐ Yes: Go to #9	☐ No: Go to #8	

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or VIIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Medication	Age/Weight	Dose	Duration	Notes
emtricitabine 200mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) PLUS raltegravir 400mg OR dolutegravir 50mg	≥ 18 years	Once daily No refills Twice daily No refills Once daily No refills	28 days	• Dosing adjustments with renal dysfunction if CrCl <60 ml/min. • Dolutegravir should not be used in pregnant women. • If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then the "alternate regimens" per CDC guidelines should be referenced and used. • Other FDA-approved regimens can be used if they become available. Formulation cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens. • Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such. • Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com • If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS (at minimum):

- Proper use of medication dosage, schedule, and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function , hepatic function , hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

Patient Information
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Key Points

- You must start the medications within 72 hours of your exposure.
- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking the medication without first asking your doctor or pharmacist.
- The most common side effects (if they do happen) are stomach upset. Taking the medication with food can help with stomach upset. Over-the- counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Adopted by Virginia Board of Pharmacy: 9/24/2021; Effective: 12/22/2021

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

_____

_____

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Emtricitabine/tenofovir disoproxil fumarate needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Etricitabine/tenofovir disoproxil fumarate and raltegravir are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with emtricitabine/tenofovir disoproxil fumarate.
- Emtricitabine/tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

Adopted by Virginia Board of Pharmacy: 9/24/2021; Effective: 12/22/2021

Adopted: 9/24/2021
Effective Date: 12/22/2021

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
- Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-9)
- Utilize the standardized PrEP Provider Fax (pg.10)

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*****Note: A pharmacy may create and use an electronic format for the PrEP Patient Intake Form, PrEP Assessment and Treatment Care Pathway, and PrEP Provider Fax if the information is identical to the forms included in this protocol.

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. ○ I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ yes □ *no*

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

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Testing:

The pharmacist must verify appropriate labs are complete. Pharmacist may order any necessary labs that are not complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test: *Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing.* NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing.	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Syphilis/Treponemal antibody: *Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.*	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
• Hepatitis B surface antigen: *Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Hepatitis C surface antigen: *Positive surface antigen indicates either acute or chronic Hepatitis C and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Pregnancy: *Positive result indicates pregnancy and PrEP should be referred to county health or a specialist physician.*	_____/_____/_____	□ *positive* □ negative	□ *Yes*
• Gonorrhea/Chlamydia: Urinalysis result: □ *reactive* □ *indeterminate* □ negative; Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative; Rectal test result: □ *reactive* □ *indeterminate* □ negative. *All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.*	_____/_____/_____		□ *Yes*
• Renal function (CrCl): SCr _____mg/dL	_____/_____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Emtricitabine and tenofovir alafenamide indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Emtricitabine and tenofovir alafenamide.*			
• <u>ALT/AST:</u> <u>Baseline + at 4-6 weeks recommended.</u>	_____/_____/_____	ALT_____u/L AST_____u/L	
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes <u>and</u> non-reactive: Proceed to question #3
- *If yes <u>and</u> reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

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3. Are all required labs complete? □ yes □ *no*

- If yes, pharmacist may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, pharmacist may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Sample language for reactive (indeterminate) STI tests:

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Emtricitabine and tenofovir disoproxil fumarate is approved for patients with a CrCl >60mL/min. • Consider Emtricitabine and tenofovir alafenamide in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
4. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Emtricitabine and tenofovir alafenamide over Emtricitabine and tenofovir disoproxil fumarate.
	CONSIDERATIONS
5. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
6. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to the Statewide Vaccine Protocol or 54.1-3408(I) of the Code of Virginia.
7. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence.

- Emtricitabine and tenofovir disoproxil fumarate is preferred due to better data in these populations.

4. Are one or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to initiate treatment in accordance with this protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to initiate treatment and dispense PrEP in accordance with this protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

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Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. • Both Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are FDA approved in these populations. May prescribe based on patient preference.	May choose Emtricitabine and tenofovir disoproxil fumarate or Emtricitabine and tenofovir alafenamide
Cis-gender female or female to male transgender man. • Only Emtricitabine and tenofovir disoproxil fumarate is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Emtricitabine and tenofovir disoproxil fumarate use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Emtricitabine and tenofovir disoproxil fumarate
NSAID use • If patient is male or a male to female transgender woman, consider Emtricitabine and tenofovir alafenamide	Emtricitabine and tenofovir alafenamide
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Emtricitabine and tenofovir alafenamide	Emtricitabine and tenofovir alafenamide
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Emtricitabine and tenofovir alafenamide.	Emtricitabine and tenofovir alafenamide
Patient is pregnant or breastfeeding • Emtricitabine and tenofovir alafenamide has not been studied in these populations. Emtricitabine and tenofovir disoproxil fumarate is approved in these populations.	Emtricitabine and tenofovir disoproxil fumarate

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/PEP and alternative dosing regimens (i.e. PrEP on demand, PrEP 2-1-1)
- Individualized strategies for optimum adherence
- Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
- Signs/symptoms of acute HIV infection and recommended actions
- Appropriate counseling regarding on-going risk for HIV and other STI acquisition
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care.
- The importance and requirement of testing for HIV, renal function, hepatitis B, hepatitis C and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Regulation 18VAC110-21-46.

Referrals to primary care provider:

- (note 1) If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 3) If a patient test has abnormal renal values and/or signs of acute renal injury, refer for urgent evaluation.

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- (note 4) If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 5) If a patient tests positive for Hepatitis C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 6) If a female patient becomes pregnant while on PrEP, refer for care.

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been initiated treatment for HIV Pre-Exposure Prophylaxis (PrEP) by _____. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Emtricitabine/tenofovir disoproxil fumarate 200/300mg; One tablet by mouth daily for 90 days
- ☐ Emtricitabine/tenofovir alafenamide 200/25mg tablets; Take one tablet by mouth daily for 90 days

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Syphilis/Treponemal antibody:	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Hepatitis B surface antigen:	_____/_____/_____	☐ *positive* ☐ negative	☐ *Yes*
• Gonorrhea/Chlamydia:	_____/_____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	
• Renal function (CrCl): ☐ CrCl >60mL/min	_____/_____/_____ ☐ CrCl 30mL/min - 60mL/min	_____ mL/min ☐ *CrCl <30mL/min*	☐ *Yes*
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	☐ *present*	☐ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	☐ *yes*	☐ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- Emtricitabine and tenofovir disoproxil fumarate is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Emtricitabine and tenofovir alafenamide may be a better option.
- Emtricitabine and tenofovir disoproxil fumarate and Emtricitabine and tenofovir alafenamide are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Emtricitabine and tenofovir disoproxil fumarate.
- Emtricitabine and tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacy monitoring of HIV PrEP:

- The pharmacy initiating treatment and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at (855) 448-7737. For information about PrEP, please visit the CDC website

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